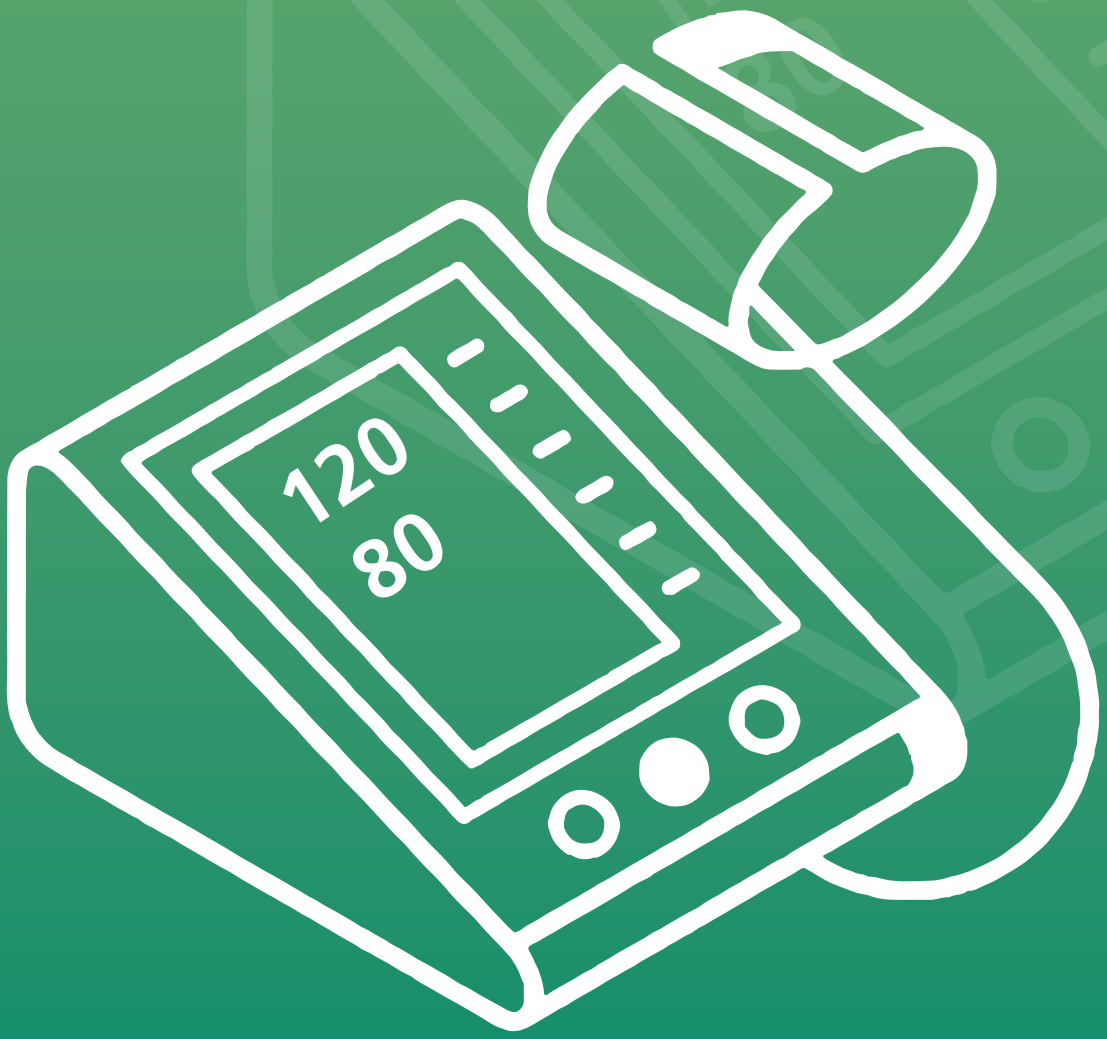
World Health Organization

Technical specifications for pre-market assessment of blood pressure measuring device with cuff, automated and semi-automated



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Contents

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WHO secretariat

Sasikala Thangavelu developed the specifications. Nicolo Binello (Technical Officer) and Daniela Rodriguez Rodriguez (consultant) selected the members of the TAG and ensured technical expertise and gender and regional distribution.

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Acronyms and abbreviations

BP	blood pressure
BPMD	blood pressure measuring device
EC	European Commission
EN	European standard
FSCA	field safety corrective action
GMDN	Global Medical Device Nomenclature
IEC	International Electrotechnical Commission
IMDRF	International Medical Device Regulators Forum
IMDRF nIVD ToC	International Medical Device Regulators Forum non-In Vitro Diagnostic Table of Contents
ISO	International Organization for Standardization
PQ	prequalification
QMS	quality management system
UMDNS	Universal Medical Device Nomenclature System
UNSPS	United Nations Standard Products and Services
WHO	World Health Organization

1. Introduction

The purpose of this document is to provide technical specifications for manufacturers of blood pressure measuring devices (BPMD). This document is intended mainly for manufacturers and as a reference by regulators for pre-market assessment.

Manufacturers should consider the technical specifications outlined here as minimum requirements to ensure that a BPMD has been designed, evaluated and validated in compliance with these requirements and is therefore safe and effective.

Manufacturers shall provide evidence to support the safety and performance of a BPMD and to demonstrate that it performs as intended, as declared in the indications for use.

Any BPMD that has undergone regulatory assessment by a stringent regulatory authority may proceed to an abridged assessment process, whereas other BPMDs will require a full assessment of documentation to ensure compliance with the technical specifications for pre-market approval. The regulator may also inspect manufacturing sites to ensure that they meet the technical requirements and the requirements of a fully implemented quality management system (QMS) for risk management, product stability, routine manufacture and sufficient capacity to ensure reliable delivery. Independent evaluation of the technical and performance characteristic of the BPMD might be conducted to ensure that it meets the technical specifications

The final outcome of the assessment depends on:

- the results of the dossier review to determine whether it meets the technical specifications and acceptance of the corrective action plan, if required;
- the results of the site inspection(s) and acceptance of the corrective action plan, if required; and
- meeting the minimum acceptance criteria in the laboratory evaluation.

When a decision to approve a BPMD has been made, a market authorization is issued by the regulator. The manufacturer is obliged to conduct post-market activities to continue to ensure the quality, safety and performance of the WHO-prequalified BPMD. The manufacturer is also obliged to notify changes to the product or the QMS, so that these may be evaluated to determine any implications for listing.

2. Methods

The document was prepared in collaboration with members of the Technical Advisory Group (TAG) that was established to review and comment on the technical specifications. The members of the group were selected from a list of experts who had contributed to WHO technical documents related to BPMDs. In addition, WHO requested regional focal points to nominate experts in BPMD, and a call was made on biomedical engineering networks. After an initial selection of experts, the list was reviewed to ensure balanced representation of engineers, clinicians and regulators, gender distribution and representation of all six WHO regions. The selected experts were then formally invited to participate in the TAG. Those who were unable to attend were replaced by alternative experts on BPMD. All the experts completed a declaration of interests. No conflicts of interest were found.

Altogether, five TAG meetings were held in 2022, three meetings before the public consultation to review the technical specifications (on 10, 18 and 23 August 2022) and two after the public consultation, on 10 and 17 November 2022, to deliberate on the comments received in the public consultation.

The draft document was posted on the WHO website for public consultation between 1 September and 10 October 2022. Various stakeholders, including an industry association and professional associations, were informed of the consultation. Comments were received from Mr Ronny Wegner (Director R&D; Member of the German DIN Working Group), Mr Habiyarmye (Rwanda Food and Drug Administration, Rwanda) and Mr Alfonso Rosales (Pan American Health Organization).

The document is based on a review of the WHO technical series on medical devices, the technical specifications for BPMDs, Pan American Health Organization documents, documentation from the BPMD validation website, BPMDs available on the market, BPMDs approved by stringent regulatory agencies and analysis of international and regional standards on BPMDs (see references). It includes a discussion and comparison of adequately tested and validated BPMDs and standards to build consensus for the global market.

In this document, the following verbal forms are used:

- "shall" indicates that the manufacturer is required to comply with the technical specifications;
- "should" indicates that it is recommended that the manufacturer comply with the technical specifications but is not required to do so; and
- "may" indicates that the technical specifications are suggested for testing but are not requirements.

The document will be updated regularly as new information becomes available.

3. Application of these specifications

The BPMD manufacturer shall comply with the specifications in this document and provide evidence that the BPMD is safe and effective and performs as intended by the manufacturer and therefore conforms to the essential principles of safety and performance of the device. The manufacturer shall comply with the requirements for establishment as a manufacturer, medical device technical specifications and quality management procedures and submit documentation as evidence as prescribed in Non-In Vitro Diagnostic Medical Device Market Authorization Table of Contents.

4. Other guidance documents

This document can be complemented with other WHO resources, including:

- Technical guidance series for WHO prequalification – Diagnostic assessment *(1)*
- WHO prequalification *(2)*
- Hypertension *(3)*
- Medical devices *(4)*
- Affordable technology; BPMD for low-resource settings *(5)*
- WHO technical specification for automated non-invasive BPMD with cuff *(6)*
- WHO list of priority medical devices for management of cardiovascular diseases and diabetes *(7)*
- Technical resources relevant to the accuracy of BP measurement *(8)*
- Regulatory pathway to the exclusive use of validated BPMD *(9)*

5. Technical specifications for blood pressure measuring devices

5.1 Intended use

This document refers only to semi-automated, automated and fully automated non-invasive upper-arm BPMDs with cuffs for use in adults. The BPMD referred to in this document shall be based on the oscillometric technique for blood pressure (BP) measurement, whereby BP is estimated from oscillations detected during inflation or deflation of the BPMD cuff with proprietary algorithms that differ by manufacturer and for models from the same manufacturer. The technique shall not include Korotkoff sounds; instead, the cuff occludes an artery (typically the brachial artery) and acts as a transducer to detect the small variations in intracuff pressure that occur with changes in heartbeat-induced pulse volume at different cuff pressures. The maximal oscillation during cuff inflation or deflation corresponds to the mean arterial pressure. This measured value is used to estimate systolic and diastolic BP with proprietary algorithms. In these devices, a microprocessor inflates and deflates the cuff.

A BPMD intended for market authorization shall be accompanied by a sufficiently detailed statement of intended use, which shall also indicate the type of BPMD. The intended use of the BPMD is to measure BP and pulse rate in adults.

5.2 Intended environment or setting for use

The BPMD is intended for use in doctors' offices, primary health care, homes or ambulatory settings. The intended users of BPMD are health-care professionals and home users.

5.3 Scope

This document specifies the technical specification for the following non-invasive BPMDs:

- semi-automated, automated and fully automated non-invasive upper-arm BPMDs with cuffs for use in adults; and
- professional and home use and automated ambulatory devices for clinical evaluation of BP.

BPMDs for children and neonates and for use in critical care are excluded.

5.4 Diversity of product types and users

Electronic BP devices are used to measure and display arterial BP. They operate by an automated or semi-automated inflation and deflation system, with a cuff applied to an extremity. The cuff is usually positioned on the upper arm for even compression of the brachial artery, which is the recommended clinical location for BP measurement. BPMDs can be grouped into three categories according to the cuff inflation and deflation mechanism: semi-automated, automated and fully automated.

In a semi-automated device, a hand pump shall be used to inflate the cuff, followed by automated deflation and determination of BP. This type of BPMD is used in health centres, district hospitals, provincial hospitals, specialized hospitals and at home.

With the automated device, the pressure cuff shall automatically inflate and deflate, during which the BP is determined (during deflation in most devices). This type of BPMD is used in health centres, district hospitals, provincial hospitals and specialized hospitals.

With a fully automated device, the pressure cuff shall also automatically inflate and deflate to determine BP; however, the device can be programmed to initiate measurements after a period of rest and with a predetermined pause between repeated measurements. This type of BPMD is also used in health centres, district hospitals, provincial hospitals and specialized hospitals. A fully automated BPMD can be used to measure BP at regular intervals over 24 h.

5.5 Applicability of supporting evidence for the blood pressure measuring device under review

Technical documentation

The manufacturer shall submit supporting documents, QMS reports, performance reports and validation reports as evidence for assessment. The reports shall be from a laboratory accredited by the International Laboratory Accreditation Cooperation.

Training

The manufacturer shall provide training material or instructions for use or a user manual to end-users of the BPMD. The manufacturer shall provide a list of proposed user training and operating manuals and user manuals (online and printed). The manufacturer shall provide online training (preferable) or on-site training (if available). The manufacturer shall provide a simple video or step-by-step instructions on use of the BPMD.

Warranty

The manufacturer shall provide information on warranty for a minimum of 2 years to end-users of the BPMD.

Maintenance

The manufacturer shall provide information on technical support and maintenance to end-users of the BPMD.

Manuals

The manufacturer shall provide a manual, instructions for use and a service manual for the BPMD to end-users, in both printed and electronic formats if requested by a country.

Service manuals, including initial set up, troubleshooting and routine maintenance shall be provided to end-users.

The instructions for use should, when possible, comply with labelling principles for medical devices and in-vitro medical devices of the International Medical Device Regulators Forum *(10)*.

Spare parts

The manufacturer shall ensure the availability of spare parts after the warranty period for 5 years after discontinuation by the manufacturing factory.

A list of all spare parts and accessories, with part numbers and contact details for parts supply, will be provided.

User care

The manufacturer shall list care to be provided by the user.

6. Table of requirements for the blood pressure measuring device under review

The table of requirements is based on International Medical Device Regulators Forum (IMDRF) Non-In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IMDRF nIVD ToC) format to assist manufacturers in submitting documentation and evidence similar to that for market authorization or for product registration submission, described in the IMDRF document IMDRF/RPS WG/N13 FINAL:2019 (Edition 3). The classification matrix for the IMDRF nIVD ToC is provided in the Annex, in which the chapters and subheadings are labelled and numbered in the IMDRF ToC format. The classification matrix defines whether a heading is required, not required, optional or conditionally required for a given submissions. As the IMDRF ToC is comprehensive, not all subheadings are required for each submission by a regulatory agency. The numbering of subheadings in Table 1 is therefore not always continuous. This is done to maintain consistency between the numbers of sections required in a product dossier for assessment and those of the IMDRF ToC format. The ToC for BPMD is shown in Table 1.

The information submitted in the IMDRF nIVD ToC should be supported by relevant documents, such as copies of labels, certificates and reports. Every supporting document referenced in the IMDRF nIVD ToC must be submitted in full (i.e. all the pages of a document). The documents must be legible and valid. All certificates or reports submitted must be signed and dated by the person issuing the report, who should be authorized to issue such documents.

Table 1. Table of requirements for BPMDs

1 Regional administrative		Description
1.01	Cover letter	The manufacturer should indicate the type of submission submitted.
1.02	Submission table of contents	The manufacturers should submit documentation and evidence similar to that for market authorization or for product registration submission of Non-In Vitro Diagnostic Medical Device
1.03	List of terms and acronyms	Definition of terms and acronyms used in this document.
1.04	Application form for administrative Information	The name, full address, primary contact information of the applicant manufacturer. The manufacturer shall provide the name and address of the manufacturing site. The names and addresses of all manufacturing site(s) that are fully owned subsidiary(ies) or contractor(s) of the legal manufacturer shall be provided.
1.05	Listing of device(s)	The manufacturer shall provide a complete list of configurations of medical devices subject to the submission, including any accessories.
1.06	Quality management system, full quality system or other regulatory certificates	The manufacturer shall use a QMS based on ISO13485:2016 or equivalent certification, accredited by an international Accreditation Forum Multilateral Recognition Arrangement signatory accreditation body. The validity of the certificate shall be specified.
1.07	Free sale certificate and certificate of marketing authorization	A list of free sale certificates obtained for various countries shall be provided.

		A list of countries in which the medical device is marketed shall be provided, which includes: Copies of approval letter(s) from a reference agency, e.g. • Food and Drug Administration, United States of America (USFDA) 510(k) clearance • European Union declaration of conformity and European Commission (EC) certificate • Japan: Ministry of Health, Labour and Welfare. Premarket certification from a Japanese registered certification body and the Pharmaceutical and Medical Devices Agency), premarket approval from the Ministry of Health, Labour and Welfare • Canadian Medical Device Requirements, Health Canada medical device licence • Therapeutic Goods Administration Australia licence, • Etc. For devices marked Conformité européenne, the European Union declaration of conformity by the product owner must be submitted, in addition to the European Commission certificate issued by the notified bodies
1.08	Expedited review documentation	The report should indicate whether expedited review has been granted by a regulatory authority. The related evidence certificate and or documentation shall be submitted.
1.09	User fees	Application fees
1.10	Pre-submission correspondence and previous regulator interactions	The manufacturer shall provide details of pre-submission correspondence, previous interactions with a regulator and the status of the submission.
1.11	Acceptance for review checklist	The manufacturer shall provide the acceptance for review checklist in the marketing submission.
1.12	Statements, certifications, declarations of conformity	The manufacturer shall provide statements, certificates or declarations of conformity to the technical specifications and the requirements stated in this document.
1.12.01	Performance and voluntary standard	The manufacturer shall list the relevant performance and voluntary standards of the product.
1.12.02	Environmental assessment	The manufacturer shall attest environmental assessment report
1.12.03	Clinical trial certifications	Clinical trial certificate of the product
1.12.04	Indications for use statement with Rx and/or OTC designation enclosure	The manufacturer shall state the indication for use of the product
1.12.05	Truthful and accurate statement	The manufacturer shall attest to the truthfulness and accuracy of the statement of the submission.
1.12.06	USFDA class III summary and certification	Manufacturer shall submit relevant USFDA
1.12.07	Declaration of conformity	The manufacturer shall provide statements, certificates or declarations of conformity to the technical specification and the requirements stated in this document

2 Submission context		
2.01	Chapter table of contents	
2.02	General summary of submission	Introductory description of the medical device, the intended use and indications for use of the device. If the medical device has any unique or novel feature or characteristic, a description must be provided. The manufacturer shall provide the name and address of the manufacturing site. All manufacturing site(s) is (are) a fully owned subsidiary(ies) or contractor(s) of the legal manufacturer. The name of the responsible person and contact person shall be provided and a list of countries in which the medical device is marketed.
2.03	Summary and certifications for premarket submissions	The manufacturer shall attest summary and list of premarket submission of the product
2.04	Device description	Electronic BP monitor Specific type or variation (optional) Automated, fully automated, or semi-automated sphygmomanometer
2.04.01	Comprehensive device description and principle of operation	A comprehensive description of the device, including technology, functionalities and features. A labelled pictorial representation (diagrams, photos, drawings) should be provided if applicable.
2.04.01.01	Global Medical Device Nomenclature (GMDN) name:	Automatic-inflation electronic sphygmomanometer
2.04.01.02	GMDN code/category	(GMDN members can access site for more information) Automatic, electronic, oscillometric
2.04.01.03	UMDNS name: https://www.ecri.org/solutions/umdns	Sphygmomanometer, electronic, automatic, oscillometric
2.04.01.04	UMDNS code	(ECRI members can access site for more information)
2.04.01.05	United Nations Standard Products and Services (UNSPS) code (optional):	C9006 Aneroid sphygmomanometer
2.04.01.06	European medical device nomenclature: https://webgate.ec.europa.eu/dyna2/emdn/	NON–INVASIVE BLOOD PRESSURE MONITORING INSTRUMENTS. Z1203020302
2.04.01.07	Alternative name(s) (optional)	Non-invasive BP monitor; oscillometric sphygmomanometer; oscillotonometer; spot-check monitor; spot-checking; sphygmomanometer, automatic
2.04.01.08	Keywords (optional)	Automatic electronic sphygmomanometer; non-invasive; digital automatic non-invasive BP monitor

	Type of BPMD	Automated and fully automated	Semi-automatic	Fully automated
	Clinical or other purpose; diagnosis and monitoring of hypertension; monitoring, measurement and display of arterial BP	√	√	√ (24-h BP measurement)
	Level of use (if relevant): Ambulatory care centre, primary health-care settings, pre-hospital, health centre, district hospital, provincial hospital, specialized hospital, home use (semi-automated)	Health centre, district hospital, provincial hospital, specialized hospital	Health centre, district hospital, provincial hospital, specialized hospital and home use	Health centre, district hospital, provincial hospital, specialized hospital.
	Clinical department or ward (if relevant) All areas in which screening, diagnostics or monitoring of BP takes place, except intensive and critical care units	√	√	√
	Overview of functional requirements The main unit includes controls and displays numerical data for BP. It also includes appropriately attached cuffs (probes and sensors, depending on their configuration)	√	√	√
	Measurement ranges:	√	√	√ (Manual)
	i) Pressure: 0–250 mm Hg	√	√	√ (Manual)
	ii) Pressure measurement accuracy ± 3 mm Hg and accuracy according to validation protocol	√	√	√ (Manual)
	Systolic (mm Hg)			
	i) 60–250 (for adult patients)	√	√	√
	Diastolic (mm Hg)			
	i) 40–130 mm Hg (for adult patients)	√	√	√
	Pulse (beats per min)			
	i) 30–200 (for adults)			
	ii) Accuracy ± 5% of the readout value or ± 3 beats per min	√	√	√
	Inflation pressure (mm Hg)	√	√ (Manual by inflator bulb)	√

	Type of BPMD	Automated and fully automated	Semi-automatic	Fully automated
	i) 150–250 for adults			
	Adjustable or automatically set preferred	√	√	√
	Automatically deflate if cuff pressure reaches > 300 mm Hg (adult)			
	Measurement interval, min: User selectable: ≥ five choices			√
	User selectable measurement time ≤ 60 s			√
	The display may include tabulated or graphic trends (user preference)			
	Displayed parameters:			
	The unit should display the following numerical values			
	i) systolic pressure,	√	√	√
	ii) diastolic pressure,	√	√	√
	iii) pulse rate,	√	√	√
	iv) low battery,	√	√	√
	v) current time and date			√
	Ingress protection			
	IEC 60601-1-11 – Medical electrical equipment IP requirements	IP21	IP20	IP22
	IP21 Classification for water ingress and particulate matter			
	Ingress protection			
	Alarm functions			
	Visual or audible alarm	√	√	√
	Equipment alarms required:			
	i) cuff leak	√	√	√
	ii) cuff disconnection	√	√	√
	iii) failure to take a successful reading	√	√	√
	iv) hose leak (preferable)			
	v) inflation or deflation error, including overpressure shutoff (preferable)			
	vi) low battery	√	√	√

	Type of BPMD	Automated and fully automated	Semi-automatic	Fully automated
	User-adjustable settings			
	Inflation pressure should be adjustable or set automatically according to a previous or current pressure reading or individual requirements.	√	√	√
	The time between automatic BP measurement cycles should be selectable from at least five values over a range of 1–60 min.			√
	Visual or audible alarms	√	√	√
	Essential component			
	List of configurations:			
	i) BPM	√	√	√
	ii)Tubing minimum length or air hose	√	√	√
	iii) Cuff; sizes	√	√	√
	iv) Relevant connectors and cables to transfer recorded information to another device			√
	v) Battery if portable; AC adapter – medical grade	√	√	√
	Main unit (optional)			
	i) Housing material: acrylonitrile butadiene styrene			
	ii) Buttons: acrylonitrile butadiene styrene			
	iii) Front panel: acrylonitrile butadiene styrene			
	iv) Polychlorinated biphenyl			
	v) Cuff: Polyvinyl chloride, polyester, nylon, polypropylene			
	Components (relevant)			
	Reusable cuff characteristics			
	i) Fabricated latex-free materials	√	√	√
	ii) Must use an ease-use clamping system	√	√	√
	iii) Washable	√	√	√
	iv) Cuff warranty: 2 years or 10 000 uses	√	√	√

	Type of BPMD	Automated and fully automated	Semi-automatic	Fully automated
	v) The cuff must be of the same brand and model as that used during clinical validation.	√	√	√
	Mobility, portability	Portable, table-top	√	√
	Tube characteristics			
	The connecting tubes must be detachable from other parts of the device, allowing periodic cutting of decayed ends and re-attachment	√	√	√
	Utility requirements			
	Electricity or gas supply, rechargeable batteries (if relevant); alternative energy sources can be considered, such as solar power			
	AC: operates from AC power electric line (if applicable): 100–240 V, 50/60 Hz ±10 % (as required by the country). The electrical plug must be compatible with the country's requirements.	√	√	
	DC: Battery (rechargeable or single-use) back-up allows operation for at least 1 h	4 ´ 1.5 V alkaline batteries; size AA	√	4 ´ 1.5 V alkaline batteries; size AA
	The power supply shall comply with the requirements, rules and regulations of the country of importation.	√	√	√
	Accessories, consumables, spare parts, other components			
	Accessories (if relevant)			
	The equipment must be compatible with the following cuff sizes (quantities and types must be confirmed by the health authorities):	√	√	√
	Reusable BP cuff small adult (25–36 cm)	√	√	√
	Reusable BP cuff adult (34–43 cm)	√	√	√

	Type of BPMD	Automated and fully automated	Semi-automatic	Fully automated
	The sizes of the cuffs depend on the manufacturer but should not deviate by ± 5 cm from the stated sizes and should be tested for accuracy.	√	√	√
	Spare parts (if relevant)			
	Rubber tube (length > 30 cm)	√	√	RS232C Connectivity for data output to computer and printer
	Tubing, valve	√	√	√
	Other components (if relevant)	√	√	√
	Protective case			
2.04.02	Description of device packaging			
	Shelf life (if relevant): 10 years			
	Transport and storage (if relevant)			
	Storage environment relative humidity: 10–95%			
	Storage environment temperature: –20–60 °C			
	Normal working conditions			
	Temperature: 5–40 °C			
	Relative humidity: 15–90%			
	Atmospheric pressure: 700–1060 kPa			
	Package validation			
	General specifications and validation methods for non-sterile medical device packages in good distribution practice principles based on ISO/DIS 23417			
2.04.03	History of development			
2.04.04	Reference and comparison to similar and/or previous generations of the device			
2.04.05	Substantial equivalence discussion			
2.05	Indications for use and/or intended use and contraindications			

2.05.01	Intended use; intended purpose; intended user; indications for use	
2.05.02	Intended environment or setting for use	
2.05.03	Paediatric use	
2.05.04	Contraindications for use	The manufacturer shall list the contraindications, which are a general description of the disease or condition and the patient population for which the device should not be used.
2.06	Global market history	Includes the list of regulatory approvals or marketing clearances obtained, including the registration status and status of any pending request for market clearance: • global marketing history • global incident reports and recalls • important safety and performance information, with a summary of reports of reportable adverse events or incidents, recall and field corrective action • sales, incident and recall rates • list of records of sales, incidents and rates • evaluation and inspection reports • the latest inspection reports
2.06.01	Global market history	The history of the device, including where it is currently authorized to be marketed and the experience in those region(s) (e.g., any incidents and/or recalls) • List of countries in which the medical device is marketed • Date (accurate to MMYYYY) and country in which the device was first introduced for commercial distribution, globally • Registration status (i.e., submitted, not submitted, pending approval, rejected or withdrawn) and approved intended use and indications of the medical device in reference agencies, in tabular format. If the device has been withdrawn or rejected by any reference agencies, the reason for rejection or withdrawal is to be provided. • Important safety and performance information, including summary of reportable incident reports and recall • Global incident reports and recalls • Latest inspection reports

2.06.02	Global incident reports and recalls	• The manufacturer shall include a summary of reportable incidents and recalls of the medical device since its first introduction on the global market, in tabular format. • The manufacturer shall ensure that all incidents due to device failure and personal injury are investigated and reported to the health-care delivery organization. The establishment shall carry out corrective and preventive actions to eliminate or reduce the risk of recurrence of such incidents. • If there have been no incidents, the manufacturer shall provide an attestation on company letterhead that there have been no adverse events since commercial introduction of the device globally. • The report shall comply with the medical device regulation and policies of the importing country. • The report should include ongoing incident reports and their status.
		The manufacturer shall establish an effective procedure for recall, describing the actions to be taken in initiating and implementing timely recall to meet the requirements of the medical device regulation and policies of the importing country. The manufacturer shall notify the health-care delivery organization and regulatory authority, advise users and facilitate removal of the BPMD from service, if required. A summary will be provided of recalls of the medical device since its first introduction onto the global market, including ongoing recalls and status.
		If there have been no adverse events or field safety corrective actions (FSCAs), the manufacturer shall provide an attestation on company letterhead that there have been no adverse events or FSCAs since commercial introduction of the device globally.
2.06.03	Sales, incident and recall rates	The manufacturer shall list the sales, incident and recall rates of the product
2.06.04	Evaluation and inspection reports	The manufacturer shall report planned changes in product design specifications, manufacturing location and manufacturing methods or ingredients to WHO. The manufacturer shall submit the latest evaluation and inspection reports

2.07	Other submission context information	The manufacturer shall establish proper, effective procedures for field corrective action, in compliance with the medical device regulation and policies of the importing country. The manufacturer shall include a summary of FSCAs for the medical device since its introduction onto the global market. For FSCAs that are "open", the manufacturer shall provide a description of any analysis and/or corrective and preventive actions undertaken.
		The manufacturer shall report planned changes in product design specification, manufacturing location and manufacturing methods or ingredients to WHO
		The manufacturer shall issue a declaration that the equipment will not be discontinued within the next 5 years
3 Non-clinical evidence		
3.01	Chapter table of contents	
3.02	Risk management Risk analysis describing the risks identified, severity of harm and probability of occurrence, including mitigation measures. A risk management report is to be submitted to substantiate that all known and foreseeable risks have been reasonably mitigated and the residual risks have been reduced or controlled to an acceptable level.	The manufacturer shall submit complete documentation on risk management based on ISO 14971:2007 Medical devices – Application of risk management to medical devices, which consists of: i) risk management report ii) risk analysis report iii) risk management plan
3.03	Essential principles checklist	The manufacturer shall identify the essential principles that are applicable to the device and the general rule or method used to demonstrate conformity to each applicable essential principle. The rules or methods that may be used include compliance with recognized or other standards, state-of-the-art or internal industry methods, and comparisons with other, similar marketed devices. The specific documents related to the rule or method used to demonstrate conformity with the essential principles should be referenced in this element. Evidence of conformity should be provided in a table entitled "Essential principles conformity checklist".
3.04	Standards	In designing and manufacture of the BPMD, the manufacturer shall comply with the standards listed below.
3.04.01	List of standards	Applicable list of standards of the product
3.04.02	Declaration and/or certification of conformity	The manufacturer shall attest declaration or certification of conformity of the product to the standards and the technical specification

3.05	Non-clinical studies, e.g., physical tests, biocompatibility studies, animal studies and software verification and validation studies Metrological requirements, shelf-life studies and projected useful life	The manufacturer shall attest relevant non clinical test reports of the product
3.05.01	Physical and mechanical characterization	Drop test IEC 60601-1:2005, AMD1:2012, AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
		Water ingress test IEC 60529:1989, AMD2:2013, COR1:2019 Corrigendum 1 – Amendment 2 – Degrees of protection provided by enclosures (IP code)
3.05.01.01	[Study description, study identifier, date of initiation]	
3.05.01.01.01	Summary	
3.05.01.01.02	Full report	
3.05.01.01.03	Statistical data	
3.05.02	Chemical and material characterization	
3.05.02.01	[Study description, study identifier, date of initiation]	
3.05.02.01.01	Summary	
3.05.02.01.02	Full report	
3.05.02.01.03	Statistical data	
3.05.03	Electrical systems: safety, mechanical and environmental protection, and electromagnetic compatibility	IEC 60601-1:2005, amendment (AMD)1:2012, AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2014, AMD1:2020 Medical electrical equipment – Parts 1–2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
3.05.03.01	[Study description, study identifier, date of initiation]	
3.05.03.01.01	Summary	
3.05.03.01.02	Full report	
3.05.03.01.03	Statistical data	
3.05.05.01	Software or firmware description	
3.05.05.02	Hazard analysis	

3.05.05.03	Software requirement specification	
3.05.05.04	Architecture design chart	
3.05.05.05	Software design specification	
3.05.05.06	Traceability analysis	
3.05.05.07	Software development environment description	
3.05.05.08	Software verification and validation	IEC 62304:2006 Medical device software — Software life cycle processes
3.05.05.08.01	[Study description, study identifier, date of initiation]	
3.05.05.08.01.01	Summary	
3.05.05.08.01.02	Full report	
3.05.05.08.01.03	Statistical data	
3.05.05.09	Revision level history	
3.05.05.10	Unresolved snomalies (bugs or defects)	
3.05.05.11	Cybersecurity	
3.05.05.12	Interoperability	
3.05.06	Biocompatibility and toxicology evaluation	ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
3.05.06.01	[Study description, study identifier, date of initiation]	
3.05.06.01.01	Summary	
3.05.06.01.02	Full report	
3.05.06.01.03	Statistical data	
3.05.07	Non-material-mediated pyrogenicity	
3.05.07.01	[Study description, study identifier, date of initiation]	
3.05.07.01.01	Summary	
3.05.07.01.02	Full report	
3.05.07.01.03	Statistical data	
3.05.08	Safety of materials of biological origin (human or animal)	
3.05.08.01	Certificates	
3.05.08.02	[Study description, study identifier, date of initiation]	
3.05.08.02.01	Summary	

3.05.08.02.02	Full report	
3.05.08.02.03	Statistical data	
3.05.09	Sterilization validation	N/A
3.05.09.01	End-user sterilization	N/A
3.05.09.01.01	[Study description, study identifier, date of initiation]	N/A
3.05.09.01.01.01	Summary	N/A
3.05.09.01.01.02	Full report	N/A
3.05.09.01.01.03	Statistical data	N/A
3.05.09.02	Sterilization	N/A
3.05.09.02.01	[Study description, study identifier, date of initiation]	N/A
3.05.09.02.01.01	Summary	N/A
3.05.09.02.01.02	Full report	N/A
3.05.09.02.01.03	Statistical data	N/A
3.05.09.03	Residual toxicity	N/A
3.05.09.3.01	[Study description, study identifier, date of initiation]	N/A
3.05.09.3.01.01	Summary	N/A
3.05.09.3.01.02	Full report	N/A
3.05.09.3.01.03	Statistical data	N/A
3.05.09.4	Cleaning and disinfection validation	N/A
3.05.09.4.01	[Study description, study identifier, date of initiation]	N/A
3.05.09.4.01.01	Summary	N/A
3.05.09.4.01.02	Full report	N/A
3.05.09.4.01.03	Statistical data	N/A
3.05.09.5	Reprocessing of single-use devices validation data	N/A
3.05.09.5.01	[Study description, study identifier, date of initiation]	N/A
3.05.09.5.01.01	Summary	N/A
3.05.09.5.01.02	Full report	N/A
3.05.09.5.01.03	Statistical data	N/A
3.05.10	Animal testing	N/A
3.05.10.01	[Study description, study identifier, date of initiation]	N/A
3.05.10.01.01	Summary	N/A
3.05.10.01.02	Full Report	N/A
3.05.10.01.03	Statistical data	N/A

3.05.11	Usability and human factors	IEC 62366-1:2015, EN 62366 Medical devices Part 1: Application of usability engineering to medical devices IEC 60601-6 (added recently) Parts 1–6: General requirements for basic safety and essential performance – Collateral standard: Usability
3.05.11.01	[Study description, study identifier, date of initiation]	
3.05.11.01.01	Summary	
3.05.11.01.02	Full report	
3.05.11.01.03	Statistical data	
3.06	Non-clinical bibliography	
3.07	Expiration period and package validation	
3.07.01	Product stability	Evidence to support product stability and package integrity during the claimed shelf-life. If applicable, both real-time and accelerated stability studies are to be submitted. If real-time ageing has not been performed, adequate justification must be provided.
3.07.01.01	[Study description, study identifier, date of initiation]	N/A
3.07.01.01.01	Summary	
3.07.01.01.02	Full report	
3.07.01.01.03	Statistical data	
3.07.02	Package validation	
3.07.02.01	[Study description, study identifier, date of initiation]	
3.07.02.01.01	Summary	
3.07.02.01.02	Full report	
3.07.02.01.03	Statistical data	
3.08	Other non-clinical evidence	
3.08.01	[Study description, study identifier, date of initiation]	
3.08.01.01	Summary	
3.08.01.02	Full report	
3.08.01.03	Statistical data	
Chapter 4 – Clinical evidence		
4.01	Chapter table of contents	
4.02	Overall clinical evidence summary	

4.02.01	Clinical evaluation report Clinical validation of clinical accuracy of non-invasive BPMD	Based on ESH/AAMI/ISO 81060-2:2018; single universal standard Part 3 Accuracy should be validated independently by institutions certified or identified as capable by relevant regulatory entities and according to standard validation protocols.
		Clause 4.3 ISO81060-2:2018: The results of clinical studies of sphygmomanometers that have been investigated according to previous versions of ISO 81060-2 remain valid. A clinical investigation need not be repeated to comply with this document.
	Standardized protocols for validating the clinical accuracy of non-invasive BPMDs; clinical validation based on ISO 81060-2:2018 Requirements for various parameters of the universal validation standard based on ISO 81060-2:2018	The clinical studies shall involve a minimum of 85 subjects.
	Subject requirements; Minimum 85 subjects based on ISO 81060-2:2018	i) Numbers
		ii) Gender distribution
		iii) Age distribution
		iv) Limb size distribution
		v) BP distribution
		vi) Special patient population
	Clinical investigation method with a reference sphygmomanometer	i) Numbers
		ii) Subject preparation
		iii) Observer preparation
		iv) Reference readings
		v) Clinical investigation methods
		a. Same arm sequential method
		b. Opposite limb simultaneous method
		vi) Additional requirements for a sphygmomanometer intended for use in ambulatory monitoring
	Limb size distribution Minimum total of 85 subjects based on ISO 81060-2:2018	a. For a sphygmomanometer intended for use with a single cuff size:
		1) at least 40% of subjects shall have a limb circumference within the upper half of the specified range of use of the cuff;
		2) at least 40% of subjects shall have a limb circumference within the lower half of the specified range of use of the cuff;
		3) at least 20% of subjects shall have a limb circumference within the upper quarter of the specified range of use of the cuff;

		4) at least 20% of subjects shall have a limb circumference within the lower quarter of the specified range of use of the cuff;
		5) at least 10% of subjects shall have a limb circumference within the upper octal of the specified range of use of the cuff; and
		6) at least 10% of subjects shall have a limb circumference within the lower octal of the specified range of use of the cuff.
		b. For a sphygmomanometer intended for use with several cuff sizes:
		1) each cuff size shall be tested on at least ½ × *n* of the total number of subjects, where *n* is the number of cuff sizes; and
		2) at least 40% of the subjects shall have a limb circumference within the upper half of the specified range of use of the cuff; and
		3) at least 40% of the subjects shall have a limb circumference within the lower half of the specified range of use of the cuff.
	Blood pressure distribution	a. At least 5% of the reference BP readings shall have a systolic BP ≤ 100 mm Hg (13.33 kPa).
		b. At least 5% of the reference BP readings shall have a systolic BP ≥ 160 mm Hg (21.33 kPa).
		c. At least 20% of the reference BP readings shall have a systolic BP ≥ 140 mm Hg (18.66 kPa).
		d. At least 5% of the reference BP readings shall have a diastolic BP ≤ 60 mm Hg (8.0 kPa).
		e. At least 5% of the reference BP readings shall have a diastolic BP ≥ 100 mm Hg (13.33 kPa).
		f. At least 20% of the reference BP readings shall have a diastolic BP ≥ 85 mm Hg (11.33 kPa).
	Data analysis	The sphygmomanometer under test shall meet the following criteria:
	Additional requirements for a sphygmomanometer intended for use in ambulatory monitoring. Minimum of 35 subjects based on ISO 81060-2:2018	a. An additional clinical investigation shall be performed for a sphygmomanometer intended for use in ambulatory monitoring.
		1) During this clinical investigation, the subjects shall be stressed by dynamic (aerobic) exercise on a bicycle ergometer to increase their heart rate to at least 15% above their resting rate.
		2) The resting heart rate shall be recorded.
		3) The heart rate at each determination shall be recorded.
		4) The elbow and forearm shall be supported during the reference reading with the automated sphygmomanometer undergoing determination.

		5) The cuff shall be at the level of the left ventricle during the reference reading and BP determination.
		b. Clinical investigation methods
		1) Same arm sequential method
		2) Opposite limb simultaneous method
		1) The clinical investigation shall involve a minimum of 35 subjects.
		2) An ambulatory monitoring study shall be exempt from the requirements of 5.1.1, 5.1.3, 5.1.4 and 5.1.5. of the standards.
		3) At least 30% of the subjects shall have a resting systolic BP > 140 mm Hg (18.66 kPa).
		4) An ambulatory monitoring study shall be exempt from acceptance criterion 2 of 5.2.4.1.2 or 5.2.4.2.2.
		c. For the same arm sequential method of 5.2.4.1, replace the reference BP variation exclusion criteria of 5.2.4.2.1 with the following:
		1) Data for the subject shall be excluded if any two sequential:
		i) reference systolic BP readings differ by more than 8 mm Hg (1.07 kPa); or
		ii) reference diastolic BP readings differ by more than 6 mm Hg (0.80 kPa).
		2) The subject need not be excluded from the clinical investigation, and the series of reference readings and determinations may be continued.
		3) The initial resting reference reading and determination need not be repeated.
4.02.02	Device-specific clinical trials	Device-specific clinical trials ISO 14155:2011 Clinical investigation of medical devices for human subjects – Good clinical practice
4.02.02.01	[Trial description, protocol number, date of initiation]	
4.02.02.01.01	Clinical trial summary	
4.02.02.01.02	Clinical trial report	
4.02.02.01.03	Clinical trial data	
4.02.03	Clinical literature review and other reasonable known information	
4.03	Institutional review board-approved informed consent forms	

4.04	Investigators' sites and institutional review board contact information	
4.05	Other clinical evidence	IEC 80601-2-30:2018 Medical electrical equipment – Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
		ISO/IEEE 11073-10407:2010 (Part 10407: Device specialization – blood pressure monitor
		DS/EN 1060-3, 2009; non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical BP measuring systems
4.05.01	[Study description, study identifier, date of initiation]	
4.05.01.01	Summary	
4.05.01.02	Full report	
4.05.01.03	Statistical data	
5 Labelling and promotional material		
5.01	Chapter table of contents	
5.02	Product and package labels	Will include a description of the product and package labels materials provided by the manufacturer. Primary and secondary labels in their original colour for the device and its accessories as applicable shall be provided. The proposed labelling should be sufficient to describe the device, its intended use and directions for its use (at least in English). The symbols used in the labels and information supplied shall comply with ISO 15223-1:2016 and EN ISO 20417:2021/IEC980:2008 or equivalent should be considered. https://www.iso.org/standard/69081.html https://www.iso.org/standard/67943.html The labelling shall comply with the requirements, rules and regulations of the country of importation
		A complete set of labelling associated with the product must be provided. The information provided must be the same as that reviewed and accepted by the national regulatory authority.

	Information on the label	Sample of labels on the device and its packaging are to be provided. The proposed labelling should be sufficient to describe the device, its intended use and instruction for its use (at least in English). The manufacturer must confirm the availability of product labelling in several languages. The labelling should contain: • name and/or trademark of the manufacturer and contact details • model or product reference • lot and batch number • model number • information on particular storage conditions (temperature, pressure, light, humidity) • shelf life ISO 15223-1:2016 and EN ISO 20417:2021 or equivalent should be considered. https://www.iso.org/standard/69081.html
	Symbols	ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	Any identification or coding	Unique device identification Naming code and term as per any of the following nomenclatures: GMDN, UMDNS, UNSPSC or EMDN
5.03	Package Insert/Instructions for Use	The manufacturer shall include the procedures and methods for safe use of the medical device. Instructions necessary to use the device safely shall, to the extent possible, be included on the device itself and/or on its packaging in other formats or forms. This should include information on indications, contraindications, warnings, precautions, potential adverse effects and the conditions of normal use to maintain the safety and effectiveness of the device
	Warnings	The manufacturer shall provide information on specific hazard alerts that a user requires before using the device.
	Precautions	The manufacturer shall indicate the precautions for special care necessary for safe, effective use of the device.
5.04	e-labelling	
5.05	Physician labelling	
5.06	Patient labelling	
5.07	Technical or operators' manual	
5.08	Patient file stickers or cards and implant registration cards	

5.09	Product brochures	
5.10	Other labelling and promotional material	
6A Quality management system procedures		
6A.01	Cover letter	
6A.02	Chapter table of contents	
6A.03	Administrative	
6A.03.1	Product description	
6A.03.2	General manufacturing information	Name and address of all manufacturers, including contract manufacturers, must be submitted.
6A.03.3	Required forms	
6A.04	Quality management system procedures	
6A.05	Management responsibilities procedures	
6A.06	Resource management procedures	
6A.07	Product realization procedures	
6A.08	Design and development procedures	
6A.09	Purchasing procedures	
6A.10	Production and service controls procedures	
6A.11	Control of monitoring and measuring devices procedures	
6A.12	QMS measurement, analysis and improvement procedures	
6A.13	Other quality system procedures information	
6B Qality management system device-specific information		
6B.01	Chapter table of contents	
6B.02	Quality management system information	
6B.03	Management responsibilities information	
6B.04	Resource management information	
6B.05	Device-specific quality plan	
6B.06	Product realization information	
6B.07	Design and development information	
6B.08	Purchasing information	

6B.09	Production and service controls information	Manufacturing process flow diagram
6B.10	Control of monitoring and measuring devices information	Calibration shall be performed against a reference manometer, such as an electronic sensor with high accuracy of ± 0.1 mm Hg, and compared with a well-maintained mercury sphygmomanometer or other recognized gold standard with a rated accuracy of only ± 3 mm Hg (0.4 kPa) The manufacturer shall perform all required calibrations for the above test equipment every year or according to the manufacturer's recommendation and shall ensure traceability accordingly.
6B.11	QMS measurement, analysis and improvement information	
6B.12	Other device-specific QMS information	

7. Standardized protocols for validating the clinical accuracy of non-invasive BPMDs; clinical validation based on ISO 81060-2:2018

Table 2. Requirements for various parameters of the universal validation standard based on ISO 81060-2:2018

3.1	Subject requirements	i) Numbers
		ii) Gender distribution
		iii) Age distribution
		iv) Limb size distribution
		v) BP distribution
		vi) Special patient population
3.2	Clinical investigation method with a reference sphygmomanometer	i) Subject preparation
		ii) Observer preparation
		iii) Reference readings
		iv) Clinical investigation methods
		a. Same arm sequential method
		b. Opposite limb simultaneous method
		v) Additional requirements for a sphygmomanometer intended for use in ambulatory monitoring
3.3	Limb size distribution	a. For a sphygmomanometer intended for use with a single cuff size:
		1) at least 40% of subjects shall have a limb circumference within the upper half of the specified range of use of the cuff;
		2) at least 40% of subjects shall have a limb circumference within the lower half of the specified range of use of the cuff;
		3) at least 20% of the subjects shall have a limb circumference within the upper quarter of the specified range of use of the cuff;
		4) at least 20% of the subjects shall have a limb circumference within the lower quarter of the specified range of use of the cuff;
		5) at least 10% of the subjects shall have a limb circumference within the upper octal of the specified range of use of the cuff; and
		6) at least 10% of the subjects shall have a limb circumference within the lower octal of the specified range of use of the cuff.
		b. For a sphygmomanometer intended for use with several cuff sizes:
		1) each cuff size shall be tested on at least ½ × n of the total number of subjects, where n is the number of cuff sizes; and
		2) at least 40% of the subjects shall have a limb circumference within the upper half of the specified range of use of the cuff; and
		3) at least 40% of the subjects shall have a limb circumference within the lower half of the specified range of use of the cuff.

3.4	Blood pressure distribution	a. At least 5% of the reference BP readings shall have a systolic BP ≤ 100 mm Hg (13.33 kPa).
		b. At least 5% of the reference BP readings shall have a systolic BP ≥ 160 mm Hg (21.33 kPa).
		c. At least 20% of the reference BP readings shall have a systolic BP ≥ 140 mm Hg (18.66 kPa).
		d. At least 5% of the reference BP readings shall have a diastolic BP ≤ 60 mm Hg (8.0 kPa).
		e. At least 5% of the reference BP readings shall have a diastolic BP ≥ 100 mm Hg (13.33 kPa).
		f. At least 20% of the reference BP readings shall have a diastolic BP ≥ 85 mm Hg (11.33 kPa).
3.5	Data analysis	The sphygmomanometer under test shall meet the following criteria:
		a. Criterion 1
		b. Criterion 2
	Additional requirements for a sphygmomanometer intended for use in ambulatory monitoring	a. An additional clinical investigation shall be performed for a sphygmomanometer intended for use in ambulatory monitoring
		1) During this clinical investigation, the subjects shall be stressed by dynamic (aerobic) exercise on a bicycle ergometer to increase their heart rate to at least 15% above their resting rate.
		2) The resting heart rate shall be recorded.
		3) The heart rate for each determination shall be recorded.
		4) The elbow and forearm shall be supported during the reference reading and the automated sphygmomanometer being determined.
		5) The cuff shall be at the level of the left ventricle during the reference reading and BP determination.
		b. Clinical investigation methods
		1) Same arm sequential method
		2) Opposite limb simultaneous method
		1) The clinical investigation shall comprise a minimum of 35 subjects.
		2) An ambulatory monitoring study shall be exempt from the requirements of 5.1.1, 5.1.3, 5.1.4 and 5.1.5. of the standards.
		3) At least 30% of the subjects shall have a resting systolic BP > 140 mm Hg (18.66 kPa).
		4) An ambulatory monitoring study shall be exempt from acceptance criterion 2 of 5.2.4.1.2 or 5.2.4.2.2.
		c. For the same arm sequential method of 5.2.4.1, replace the reference BP variation exclusion criteria of 5.2.4.2.1 with the following:
		1) Data for the subject shall be excluded if any two sequential:
		i) reference systolic BP readings differ by more than 8 mm Hg (1.07 kPa); or
		ii) reference diastolic BP readings differ by more than 6 mm Hg (0.80 kPa).
		2) The subject need not be excluded from the clinical investigation, and the series of reference readings and determinations may be continued.
		3) The initial resting reference reading and determination need not be repeated.

References

1. Technical Guidance Series (TGS) for WHO Prequalification – Diagnostic assessment. Principles of performance studies. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/258985/WHO-EMP-RHT-PQT-TGS3-2017.03-eng.pdf;sequence=1).

2. World Health Organization prequalification. Geneva: World Health Organization; 2023 (https://apps.who.int/iris/handle/10665/43115).

3. Hypertension. Geneva: World Health Organization; 2023 (https://www.who.int/health-topics/hypertension#tab=tab_1).

4. Medical devices. Geneva: World Health Organization; 2023 (https://www.who.int/health-topics/medical-devices#tab=tab_1).

5. Affordable technology: blood pressure measuring devices for low resource settings. Geneva: World Health Organization; 2005 (https://apps.who.int/iris/handle/10665/43115).

6. WHO technical specifications for automated non-invasive blood pressure measuring devices with cuff. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/331749).

7. WHO list of priority medical devices for management of cardiovascular diseases and diabetes. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240027978).

8. Technical note: Technical resources relevant to the accuracy of blood pressure measurement. Washington DC: Pan American Health Organization; 2020 (https://www.paho.org/en/documents/technical-resources-relevant-accuracy-blood-pressure-measurement).

9. HEARTS in the Americas: Regulatory pathway to the exclusive use of validated blood pressure measuring devices. Washington DC: Pan American Health Organization; 2021 (https://iris.paho.org/handle/10665.2/55382).

10. Table of Contents Working Group. Regulated product submissions. Non-in vitro diagnostic medical device market authorization table of contents (nIVD MA ToC). Brussels: International Medical Device Regulators Forum; 2019 (https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-nivd-dma-toc-n9.pdf).

Annex. Matrix classification of IMDRF nIVD ToC

IMDRF ToC Chapter 1 – Regional administrative		
1.01	Cover letter	R
1.02	Submission table of contents	R
1.03	List of terms and acronyms	R
1.04	Application form, administrative information	
1.05	Listing of device(s)	R
1.06	Quality management system, full quality system or other regulatory certificates	R
1.07	Free sale certificate or certificate of marketing authorization	R
1.08	Expedited review documentation	R
1.09	User fees	
1.10	Pre-submission correspondence and previous regulator interactions	R
1.11	Acceptance for review checklist	R
1.12	Statements, certificates, declarations of conformity	R
1.12.01	Performance and voluntary standard	R
1.12.02	Environmental assessment	R
1.12.03	Clinical trial certificates	R
1.12.04	Indications for use statement with Rx and/or OTC designation Enclosure	R
1.12.05	Truthful and accurate statement	R
1.12.06	USFDA class III summary and certification	NR
1.12.07	Declaration of conformity	R
1.13	Letters of reference for master files	R
1.14	Letter of authorization	NR
1.15	Other regional administrative information	NR
Chapter 2 – Submission context		
2.01	Chapter table of contents	R
2.02	General summary of submission	R
2.03	Summary and certificates for premarket submissions	R
2.04	Device description	R
2.04.01	Comprehensive device description and principle of operation	R
2.04.02	Description of device packaging	R
2.04.03	History of development	R
2.04.04	Reference and comparison with similar and/or previous generations of the device	R

2.04.05	Substantial equivalence discussion	R
2.05	Indications for use and/or intended use and contraindications	R
2.05.01	Intended use; intended purpose; intended user; indications for use	R
2.05.02	Intended environment or setting for use	R
2.05.03	Paediatric use	R
2.05.04	Contraindications to use	R
2.06	Global market hstory	R
2.06.01	Global market history	R
2.06.02	Global incident reports and recalls	R
2.06.03	Sales, incident and recall rates	R
2.06.04	Evaluation and inspection reports	R
2.07	Other submission context information	NR
Chapter 3 – Non-clinical evidence		
3.01	Chapter table of contents	R
3.02	Risk management	R
3.03	Essential principles checklist	R
3.04	Standards	R
3.04.01	List of standards	R
3.04.02	Declaration and/or certification of conformity	R
3.05	Non-clinical studies	R
3.05.01	Physical and mechanical characterization	R
3.05.01.01	[Study description, study identifier, date of initiation]	
3.05.01.01.01	Summary	R
3.05.01.01.02	Full report	R
3.05.01.01.03	Statistical data	R
3.05.02	Chemical or material characterization	R
3.05.02.01	[Study description, study identifier, date of initiation]	R
3.05.02.01.01	Summary	R
3.05.02.01.02	Full report	R
3.05.02.01.03	Statistical data	R
3.05.03	Electrical systems: safety, mechanical and environmental protection, and electromagnetic compatibility	R
3.05.03.01	[Study description, study identifier, date of initiation]	R
3.05.03.01.01	Summary	R
3.05.03.01.02	Full report	R
3.05.03.01.03	Statistical data	R

3.05.04	Radiation safety	NR
3.05.04.01	[Study description, study identifier, date of initiation]	NR
3.05.04.01.01	Summary	NR
3.05.04.01.02	Full report	NR
3.05.04.01.03	Statistical data	NR
3.05.05	Software or firmware	R
3.05.05.01	Software or firmware description	R
3.05.05.02	Hazard analysis	R
3.05.05.03	Software requirement specification	R
3.05.05.04	Architecture design chart	R
3.05.05.05	Software design specification	R
3.05.05.06	Traceability analysis	R
3.05.05.07	Software development environment description	R
3.05.05.08	Software verification and validation	R
3.05.05.08.01	[Study description, study identifier, date of initiation]	R
3.05.05.08.01.01	Summary	R
3.05.05.08.01.02	Full report	R
3.05.05.08.01.03	Statistical data	R
3.05.05.09	Revision level history	R
3.05.05.10	Unresolved anomalies (bugs or defects)	R
3.05.05.11	Cybersecurity	R
3.05.05.12	Interoperability	R
3.05.06	Biocompatibility and toxicology evaluation	R
3.05.06.01	[Study description, study identifier, date of initiation]	R
3.05.06.01.01	Summary	R
3.05.06.01.02	Full report	R
3.05.06.01.03	Statistical data	R
3.05.07	Non-material-mediated pyrogenicity	R
3.05.07.01	[Study description, study identifier, date of initiation]	R
3.05.07.01.01	Summary	R
3.05.07.01.02	Full report	R
3.05.07.01.03	Statistical data	R
3.05.08	Safety of materials of biological origin (human or animal)	O
3.05.08.01	Certificates	O
3.05.08.02	[Study description, study identifier, date of initiation]	O
3.05.08.02.01	Summary	O

3.05.08.02.02	Full report	O
3.05.08.02.03	Statistical data	O
3.05.09	Sterilization validation	NR
3.05.09.01	End-user sterilization	NR
3.05.09.01.01	[Study description, study identifier, date of initiation]	NR
3.05.09.01.01.01	Summary	NR
3.05.09.01.01.02	Full report	NR
3.05.09.01.01.03	Statistical data	NR
3.05.09.02	Manufacturer sterilization	NR
3.05.09.02.01	[Study description, study identifier, date of initiation]	NR
3.05.09.02.01.01	Summary	NR
3.05.09.02.01.02	Full report	NR
3.05.09.02.01.03	Statistical data	NR
3.05.09.03	Residual toxicity	NR
3.05.09.3.01	[Study description, study identifier, date of initiation]	NR
3.05.09.3.01.01	Summary	NR
3.05.09.3.01.02	Full report	NR
3.05.09.3.01.03	Statistical data	NR
3.05.09.4	Cleaning and disinfection validation	NR
3.05.09.4.01	[Study description, study identifier, date of initiation]	NR
3.05.09.4.01.01	Summary	NR
3.05.09.4.01.02	Full report	NR
3.05.09.4.01.03	Statistical data	NR
3.05.09.5	Reprocessing of single-use devices validation data	NR
3.05.09.5.01	[Study description, study identifier, date of initiation]	NR
3.05.09.5.01.01	Summary	NR
3.05.09.5.01.02	Full report	NR
3.05.09.5.01.03	Statistical data	NR
3.05.10	Animal testing	NR
3.05.10.01	[Study description, study identifier, date of initiation]	NR
3.05.10.01.01	Summary	NR
3.05.10.01.02	Full report	NR
3.05.10.01.03	Statistical data	NR
3.05.11	Usability and human factors	R
3.05.11.01	[Study description, study identifier, date of initiation]	R
3.05.11.01.01	Summary	R

3.05.11.01.02	Full report	R
3.05.11.01.03	Statistical data	R
3.06	Non-clinical bibliography	R
3.07	Expiration period and package validation	R
3.07.01	Product stability	R
3.07.01.01	[Study description, study identifier, date of initiation]	R
3.07.01.01.01	Summary	R
3.07.01.01.02	Full report	R
3.07.01.01.03	Statistical data	R
3.07.02	Package validation	R
3.07.02.01	[Study description, study identifier, date of initiation]	R
3.07.02.01.01	Summary	R
3.07.02.01.02	Full report	R
3.07.02.01.03	Statistical data	R
3.08	Other non-clinical evidence	NR
3.08.01	[Study description, study identifier, date of initiation]	NR
3.08.01.01	Summary	NR
3.08.01.02	Full report	NR
3.08.01.03	Statistical data	NR
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4.02.02	Device-specific clinical trials	R
4.02.02.01	[Trial description, protocol number, date of initiation]	R
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4.02.02.01.02	Clinical trial report	R
4.02.02.01.03	Clinical trial data	R
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4.03	Institutional review board-approved informed consent forms	R
4.04	Investigators' sites and institutional review board contact information	R
4.05	Other clinical evidence	R
4.05.01	[Study description, study identifier, date of initiation]	R
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R, required; NR, not required

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