

## ANNEX C – Technical Specifications

This document defines the technical specification requirements for medical items procured by Plan International Incorporated (PII). Suppliers are required to provide medical products in accordance with these specifications to comply with internationally recognised quality, safety, and efficacy standards suitable for use in PII programs.

The medical products specified include the following Lots which are defined below:

| Lot # | Medical Product Sub-Category | Definition                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1     | Pharmaceuticals              | Medicines used to prevent, diagnose, treat, or cure disease or to modify physiological functions.                                                                                                                                                                                                                                                                                                                                                                |
| 2     | Medical Devices              | <p>An article, instrument, apparatus or machine used in the prevention, diagnosis or treatment of illness whose function is physical or mechanical and not chemical.</p> <p>Medical Devices include <b>medical consumables</b> (e.g. syringes, needles, gloves, disinfectants for medical devices), <b>medical equipment</b> (e.g. stethoscope, thermometer, weighing scale), <b>laboratory equipment and supplies</b> (e.g. rapid diagnostic tests (RDTs)).</p> |
| 3     | Health Kits                  | A pre-packaged, standardised set of medical products. These may contain pharmaceuticals, medical devices and non-medical products. Specifications must be met for all categories within the kit.                                                                                                                                                                                                                                                                 |

### General Specifications

All products offered must:

- Be authorised for distribution and import (if applicable) by the National Regulatory Authority (NRA) in the destination country.
- Comply with WHO Good Storage and Distribution Practices (GSDP) throughout the supply chain.
- Always be stored or transported at the required controlled conditions following the manufacturers' instructions as indicated on the packaging.
- Be packaged to ensure protection against damage, contamination, and environmental conditions.
- Have a minimum remaining shelf life of 75% upon delivery or at least 24 months unless otherwise specified, if applicable.

### Medical Product Lot Specific Requirements

#### Lot 1 - Pharmaceuticals

All products offered must:

- Be manufactured in facilities compliant with WHO Good Manufacturing Practices (GMP) or an equivalent internationally recognised GMP standard (e.g. EU GMP). Compliance with GMP must be demonstrated through a valid certificate from a competent authority confirming that the manufacturing site has undergone inspection and meets applicable GMP standards, including one of the following:

- A NRA classified as a WHO Listed Authority (WLA)<sup>1</sup>
  - WHO Prequalification and Public Inspection Reports<sup>2</sup>
- Be manufactured to conform to standards of one of the following: WHO International Pharmacopoeia, European Pharmacopoeia (EP), British Pharmacopoeia (BP) or the United States Pharmacopoeia Convention (USP) or other equivalent WHO Listed Authority (WLA<sup>2</sup>)-recognised pharmacopoeia.
  - Be batch tested and confirmed to conform to above pharmacopoeia listed specifications.
  - Be packaged and labelled according to the following<sup>3</sup>:
    - Labelling should be in English and/or language of country of use and must include the following at a minimum:
      - Secondary packaging:
        - Brand name of product
        - International Non-proprietary Name (INN) of the active ingredient(s) and strength(s)
        - Dosage form (for products requiring reconstitution this must be made clear, e.g. Powder for solution for injection)
        - Route of administration
        - Storage conditions (for products requiring reconstitution, this should include both before and after reconstitution)
        - Batch number
        - Expiry Date
        - Name and address of manufacturer or Marketing Authorisation Holder (MAH)
        - Number of units per package
        - Primary packaging (blisters, tubes, ampoules, etc.):
        - Brand name of product (and INN(s) if space permits)
        - Strength
        - Batch number
        - Expiry date
        - For products requiring reconstitution, must also include dosage form (e.g. Powder for solution), route of administration, shelf-life after reconstitution and diluent identification; Key information can be reduced due to size restrictions but cannot compromise safety.
    - Patient information leaflets should be in English and/or language of country of use and must include the following at a minimum:
      - Product information: Brand name, INN of the active ingredient(s), excipients, strength and dosage form
      - Therapeutic indications
      - Contraindications, Warnings/precautions, Interactions, Use in pregnancy/breastfeeding
      - Instructions of use: Dosage instructions, Method of administration, Duration of treatment, Advice in case of overdose, missed dose
      - Side effects
      - Storage conditions
      - Description of appearance and pack sizes
      - Name and address of manufacturer

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<sup>1</sup> [WHO Listed Authority](#)

<sup>2</sup> [Medicines \(Finished Pharmaceutical Products/Biotherapeutic products\) - Prequalification | WHO - Prequalification of Medical Products \(IVDs, Medicines, Vaccines and Immunization Devices, Vector Control\)](#)

<sup>3</sup> [Aligns with EU GMP minimum requirements](#)

- Packaging must protect against damage sufficiently according to the product- specific requirements:
  - Dry dosage forms should be in sealed, waterproof containers
  - Liquid dosage forms should be packaged in leak-proof, unbreakable containers
  - Fragile products (such as ampoules) should be securely held in position and protected from movement and impact (e.g. in formed trays)
  - Light-sensitive products should be packed in light-protective materials
  - Outer cartons or tertiary packaging should protect from physical and environmental damage and be sufficiently labelled to allow for traceability and prevent mix-up including:
    - Brand name
    - Batch number
    - Expiry date
    - Quantity
    - Storage conditions
- Have Certificates of Analysis (CoAs) and/or Certificates of Pharmaceutical Product (CoPPs) available if required

## Lot 2 - Medical Devices

Medical Devices consist of a broad category of products and are generally classified based on their characteristics, intended use and risks. The EU Medical Device Regulations 2017/7454 divides them into the following four main classes:

- Class I: Low-risk devices, typically non-invasive or in contact with intact skin. Subcategories include:
  - Is (sterile)
  - Im (measuring)
  - Ir (reusable surgical instruments)
- Class IIa: Medium-risk devices, often invasive or active devices with limited duration of use.
- Class IIb: Higher-risk devices, including active devices that may pose a potential hazard or have a significant systemic effect.
- Class III: Highest-risk devices, such as implantable devices or long-term surgically invasive devices

Class I (non-sterile, non-measuring, non-reusable surgical instruments) items have been separated for the purpose of this document, due to their lower risk and technical specifications required.

### *Class I (non-sterile, non-measuring, non-reusable surgical instruments)*

All products offered must:

- Be provided with documentation that includes sufficient technical detail to support assessment of compliance, including intended use, specifications, and conformity declarations. This may be provided by a EU MDR Declaration of Conformity from the manufacturer, where the product is CE marked, or equivalent documentation demonstrating compliance with a WLA regulatory authority.
- Comply with the packaging and labelling requirements as listed below for other classes of medical devices.
- Meet category-specific technical and operational requirements suitable for global humanitarian deployment, including usability and environmental robustness.

### *Class I sterile, measuring, reusable surgical instruments, Class II, III*

All products offered must:

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<sup>4</sup> [Regulation - 2017/745 - EN - Medical Device Regulation - EUR-Lex](#)

- Be manufactured by a company with an ISO 13485:2016 Quality Management System (QMS) certification issued by a Certification Body accredited by a national Accreditation Body that is a signatory to the Global Accreditation Cooperation (GAC) Mutual Recognition Arrangement<sup>5</sup> (formerly called the International Accreditation Forum (IAF) Multilateral Recognition Arrangement<sup>6</sup>.) The certificate must be valid, current, and include the relevant medical devices within its scope. Equivalent internationally recognised accreditation frameworks may be accepted subject to justification.
- Have met standards of product safety, performance, clinical evidence and risk management through evidence of:
  - CE certificate (EU) under EU Medical Device/Invitro Diagnostics Regulations (MDR/IVDR), or an equivalent regulatory pathway (e.g. US FDA 510k, UKCA certificate, Health Canada MD Licence, TGA ARTG (Australia) inclusion, PMDA/MHLW (Japan) approval, WHO Prequalification)
- Be packaged and labelled according to the following<sup>7</sup>:
  - Labelling should be in English and/or language of country of use and must include the following at a minimum:
    - Device name
    - Intended purpose (if not obvious)
    - Manufacturer name and address
    - Batch number / lot number or serial number
    - Expiry date (if relevant)
    - Date of manufacture
    - Storage and handling conditions (if needed)
    - Sterility status and method (if sterile)
    - Quantity (where applicable)
    - Any warnings or precautions
    - Single-use indication (if applicable)
    - Reprocessing limitations (if reusable device)
  - Instructions for use must be included, unless it can be safely used without them and should include:
    - Intended purpose and indications
    - Target patient population
    - Contraindications
    - Warnings, precautions, and risks
    - Detailed instructions for use
    - Installation & maintenance instructions (if relevant)
    - Residual risks
    - Performance characteristics
    - Clinical benefits
    - Information on compatibility (e.g., accessories)
    - Disposal instructions (environmental/safety)
- Meet category-specific technical and operational requirements suitable for global humanitarian deployment, including usability, environmental robustness, maintenance, sterility (where applicable) and post-market surveillance capability.

## Lot 3 - Health Kits

All products offered must:

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<sup>5</sup> [Recognised ABs - Global ACI](#)

<sup>6</sup> [Recognised ABs - IAF](#)

- Meet applicable quality standards for each individual component as detailed above for Pharmaceuticals and Medical Devices.
- Have a fixed composition where substitutions are only allowed with prior approval.
- Be assembled under controlled conditions following procedures allowing for batch traceability of components.
- Be labelled with the following information on the outer packaging<sup>8</sup>:
  - Kit name and version
  - Contents summary
  - Kit Batch number
  - Kit Expiry date (the earliest expiry of any component)
  - Storage conditions (applicable to all components)

## Abbreviations

|      |                                            |
|------|--------------------------------------------|
| GMP  | Good Manufacturing Practices               |
| GSDP | Good Storage and Distribution Practices    |
| INN  | International Non-proprietary Name         |
| NRA  | National Regulatory Authority              |
| MDR  | Medical Device Regulations                 |
| PII  | Plan International Incorporated            |
| RDT  | Rapid Diagnostic Tests                     |
| WHO  | World Health Organization                  |
| WLA  | World Health Organization Listed Authority |

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<sup>8</sup> [WHO MQAS](#)