2024

MSF

INTERNATIONAL

OVERVIEW OF THE MSF QUALIFICATION PROCESS FOR MEDICAL DEVICES, IN VITRO DIAGNOSTICS AND PERSONAL PROTECTIVE EQUIPMENT

GENERAL PRINCIPLES

- MSF believe that compliance with international standards is the most reliable and efficient way to provide performing and safe medical products, including Medical Devices (MD), In Vitro Diagnostics (IVD) and Personal Protective Equipment (PPE), referred as 'MD' in this document, to prevent product-related risks for patients and healthcare workers, and to minimize the use of substandard.
- Therefore, MSF has established as a core principle in the MSF Quality Assurance Policy for Medical Products and Specialized Food that all MDs shall comply with quality recognized international standards, like products cleared and used in Highly Regulated Countries[1] (HRC) to provide the best quality of care to its patients as well as a safe working environment to its medical teams.
- In addition, MSF must comply with all applicable national regulation concerning importation processes as defined by the National Competent Authority and in accordance with the project Memorandum of Understanding (MoU) and, where existing, the MSF Host Country Agreement (HCA).

SPECIFIC RISKS DUE TO THE CONTEXT OF MSF MISSIONS

The diversity of MD (i.e. sterile, invasive, sophisticated, thermosensitive) has led most regulatory bodies to adopt a risk-based approach to determine the appropriate level of scrutiny applied to MD before their certification and clearance for use in HRC. However, some specific conditions of use in MSF missions may not have been considered in the product design validation resulting in a higher risk of loss of performance or misuse with potential serious consequences to the patients' and health workers' safety compared to its use in HRC. These include, but not limited to:

- extreme environmental conditions (e.g. temperature, humidity, dust),
- level of training of the end-users (health professionals and non-health professionals) for whom the Instructions for Use (IFU) might not be adapted,
- MSF patient's clinical profile in specific epidemiological contexts.

HARMONIZATION OF MEDICAL PRACTICES AMONG MSF PROJECTS

MSF projects (more than 450 projects in 70 countries) are run by national and international staff and are subject to high human resources turnover. To ensure the best possible quality of care to our patients and to allow our medical staff to be operational as fast as possible, MSF has defined standard clinical protocols and technical practices in many domains (surgery, obstetrics, nursing care, transfusion, laboratory, cholera treatment, etc.) along with a limited list of standard medical products and equipment considered best adapted to MSF specific needs and risks. MSF teams are specifically trained to use and to maintain those standard medical products and equipment.

[1] The International Medical Device Regulators Forum (IMDRF, previously Global Harmonization Task Force (GHTF)) founding countries: USA, Canada, Japan, Australia, EU, EFTA (Norway, Iceland, Liechtenstein and Switzerland) and UK. Current members also include Brazil, China and Russia. However, for the purpose of this document Brazil, China, Russia, and Turkey are not considered as HRCs.

MSF PROCESS FOR THE VALIDATION OF QUALITY-ASSURED SOURCES OF MEDICAL DEVICES

DEFINITION OF THE PRODUCT TECHNICAL SPECIFICATIONS

The patient and the health worker's needs are always the entry point for the validation of a medical device by MSF. The clinical relevance, in line with MSF standard protocols, the performance and the user-friendliness of the product are assessed by MSF technical referents at headquarters and translated into technical specifications in the MSF catalog, called Unicat.

REGULATORY AND QUALITY ASSESSMENT OF MD, IVD AND PPE

MSF favors the sourcing of MD and IVD that are cleared in HRC or prequalified by WHO when applicable. Therefore, MSF mostly use products that are:

- CE mark according to the Directive 93/42/EEC (MDD) or the Regulation (EU) 2017/745 (MDR) for MD, or according to the Directive 98/79/EEC (IVDD) or the Regulation (EU) 2017/746 (IVDR) for IVD and/or
- UKCA certified and/or
- USFDA cleared and/or
- In Vitro Diagnostics, male and female condoms and Intra-Uterine Devices prequalified by WHO

ISO 13485 certified manufacturers are preferred. QMS compliance in accordance with the requirements governing regulatory approvals or marketing authorizations of MD and IVD in HRC can be accepted for low-risk class products.

A product is validated if the following valid documents are provided by the supplier: Declaration of Conformity, CE/EU certificate, ISO 13485 certificate, labelling of secondary and primary packaging, Instructions for Use and stability data where applicable.

In the rare case where no certified or cleared product meeting MSF technical specifications is available, MSF conducts manufacturer audits led by a certified auditor according to ISO 13485. A risk/benefit analysis is performed to conclude on the product validation for purchase.

The product assessment is performed by MSF supply centers located in France, Belgium, and the Netherlands. Our three procurement centers are accredited by the National Competent Authority as Wholesale Distributor for Humanitarian Purposes through an inspection process on a regular basis, as well as part of the list of the European Civil Protection and Humanitarian Aid Operations (DG ECHO) as validated procurement centers for humanitarian supplies.

For PPE, MSF selects products with regulatory approval and marketing authorization issued by at least one regulatory authority from HRC and comply with relevant standards recognized by HRC (EN, ASTM, NIOSH, JIS, AS/NZA[2]). ISO 13485 certified manufacturers are preferred for PPE classified as MD, otherwise a valid and certified QMS according to the latest version of ISO 9001 can be accepted.

POST-MARKET SURVEILLANCE, COMPLAINT AND RECALL MANAGEMENT

MSF has implemented procedures to fulfill the legal obligations of manufacturers and suppliers related to post-market surveillance and management of complaints and recall. Our system allows 1. MSF to collect the quality complaints from the field and report them to the legal manufacturers through the MSF supply centers or to the supplier, 2. to implement Corrective and Preventive Actions, 3. to initiate batch recalls according to manufacturers' Field Safety Notices instructions. The system also enables MSF to detect product misuse and to monitor the proper application of MSF standard protocols, while providing continuous feedback to manufacturers and suppliers on product quality.

[2] EN for European Norm; ASTM for American Society for Testing and Material; NIOSH for National Institute for Occupational Safety and Health; JIS for Japan Industrial Standard; AS/NZS for joint Australian and New Zealand Standard

ANNEX 1: EXAMPLES OF CLASSIFICATION ACCORDING TO EU 2017/745 (MDR) AND US FDA CLASSIFICATION RULES FOR MD USED BY MSF (NOT EXHAUSTIVE)

Note: some medical devices are still on the market under the MD Directive until the transition period is over according to Regulation (EU) 2023/607. More information can be found the Factsheet for authorities in non-EU/EEA states.

EU	USA	Examples of medical devices (XXXX = MSF product nomenclature)
Class I / Ir	**Class I**	**Nonsterile items with a low potential risk** SCTD: enterostomy bag, biconical connector SDRE: bandages, non-sterile compresses, tape, thread for umbilical cord SSDC: oral syringes, medication cup SINS: EZ-IO drill SMSU: examination gloves, stethoscope, reusable surgical instruments
Class I s		**Sterile items with a low potential risk** SCTD: urine bag, urinary catheter nelaton, suction tube, extractor mucus neonate SDRE: sterile compresses, clamp for umbilical cord SINS: syringe without needle, IV giving set, pediatric infusion set SSUT: adhesive skin closure
Class IIa	**Class II**	SCTD: balloon catheter post-partum, filter breathing circuit, oxygen cannula / tube / mask, suprapubic catheter, urinary catheter foley, Penrose and Delbet drains, thoracic drains, peritoneal diagnostic set, redon, endotracheal tube, gastric tubes SDRE: kaolin-based hemostatic dressing, abdominal compress SINS: transfusion set, needles, IV catheters, syringe and IV line for pump, extension tubing, IV catheter, IO needle & dressing, scalp vein infusion set, AD and insulin syringes SMSU: electronic thermometer, surgical and gynecological gloves, amnio hook EEMD: ECG, suction pumps, powered dermatome, oxygen concentrator Single use surgical instruments, lancets, surgical staplers, blood bank fridge
Class IIb		SCTD: ureteral catheter, tracheotomy cannula SINS: blood bags SMSU: condom (no spermicide) SSUT: non-absorbable sutures Dialysis equipment, ventilators, anesthesia machines, incubator, warming blanket, defibrillator, intensive care monitoring device, insulin pen
Class III		SINS: needle for rachis or lumbar puncture, blood bags with anti-coagulant SDRE: fibrin sealant dressing, chitosan hemostatic dressing SMSU: IUD SSUT: absorbable sutures, non-absorbable mesh

ANNEX 2: CLASSIFICATION OF IVD ACCORDING TO THE EU 2017/746 (IVDR) AND THE CORRESPONDING MSF PRODUCTS OF INTEREST

Note: most IVD are still on the market under the IVD Directive until the transition period is over according to Regulation (EU) 2024/1860. More information can be found in the Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.

IVDR classification	Type of IVD	Products of interest for MSF
Class D	Devices intended to determine any of the following markers: – ABO system [A (ABO1), B (ABO2), AB (ABO3)] – Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] – Kell system [KEL1 (K)] – Kidd system [JK1 (Jka), JK2 (Jkb)] – Duffy system [FY1 (Fya), FY2 (Fyb)]	Blood grouping tests (anti-A, anti-AB, anti B, Rhesus anti-D) RH negative control tests Bedside control cards for ABO compatibility
	Devices intended to be used for the detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration	Hepatitis B (HBs-Ag) Hepatitis C (Anti-HCV) Human Immunodeficiency Virus 1/2 (Anti-HIV 1/2). Malaria
	Devices intended to be used for the detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation	Hemorrhagic fever viruses (e.g. Ebola, Marburg, Lassa, Crimean-Congo Hemorrhagic fever) SARS-CoV
Class C	Devices intended for detecting the presence of, or exposure to, a sexually transmitted agent	Neisseria gonorrhoeae Chlamydia trachomatis Human papilloma virus (HPV) Treponema pallidum
	Devices intended for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation	Bacterial pathogens: Streptococcus pneumoniae, Group B Streptococcus, Neisseria meningitidis, Haemophilus influenza type B, Listeria spp., Borrelia burgdorferi, Mycobacterium tuberculosis. - Fungal pathogens: Cryptococcus neoformans, Aspergillus spp. - Viral pathogens: Herpes simplex virus 1&2, human herpes virus 6, varicella zoster virus, enterovirus, West Nile virus, chikungunya, Dengue, Zika, hepatitis A, hepatitis E. - Parasitic pathogen: Toxoplasma gondii.
	Devices intended for management of patients suffering from a life-threatening disease or condition	Blood glucose strips
Class B	Devices intended for self-testing are classified as class C, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine, which are classified as class B	Pregnancy RDT Urine test strips
Class A	Products for general laboratory use[3], accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for *in vitro* diagnostic procedures relating to a specific examination	Specimen receptables Prepared selective culture media Pipette

[3] Some products for general laboratory use are considered neither as IVD nor as accessories. More details in the MDCG 2024-11 – Guidance on qualification of *in vitro* diagnostic medical devices