2021

MSF
INTERNATIONAL

MSF QUALIFICATION PROCESS FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTICS

MEDECINS SANS FRONTIERES

1. GENERAL PRINCIPLES

- As for the medicines, MSF imports Medical Devices (MD) and In Vitro Diagnostics (IVD) into countries under its legal and moral responsibilities. It is therefore MSF' responsibility to ensure that these products fulfill equivalent standards in terms of safety and efficacy as products cleared and used in Highly Regulated Countries (HRC) to provide the best quality of care to its patients as well as a safe working environment to its medical teams.

- 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).

  The MSF Quality Assurance for MD and IVDs takes into consideration the nature, the context and the volume of MSF medical activities worldwide.

1.1. Specific risks due to the context of the MSF missions

The diversity of MD (i.e. sterile, invasive, sophisticated, thermo sensitive) has led regulatory bodies to adopt a risk-based approach to determine the appropriate level of scrutiny for a given type of MD. Unfortunately, the risk classification defined in HRC seldom corresponds to MSF's reality of use. For example, the malaria rapid diagnostic test classified by HRCs in the least stringent / lowest risk category permits product self-certification by manufacturers, although the quality and the performance of this product is crucial to the quality of care in the countries where MSF operates. In addition, 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. 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.

1.2. Harmonisation 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 a 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 adapted to MSF specific needs and risks. MSF teams are specifically trained to use and to maintain those standard medical products and equipment.

2. MSF PROCESS FOR THE VALIDATION OF INTERNATIONAL SOURCES OF MD AND IVD

Considering the above, the MSF process for the validation of international sources of MD and IVDs is meant to minimise any preventable devices-related risks for patients' health and to ensure health workers' safety, while considering manufacturer capacity of continuous supply of acceptable and agreed quality of product.

2.1. Definition of the product technical specifications

The end-user needs (the patient and the health worker) is always the entry point for the validation of a MD. 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 level and translated into technical specifications in the internal MSF catalog of standard items.

2.2. **Regulatory and quality assessment of MD/IVD**

MSF favors the sourcing of MD and IVD that are cleared in Highly Regulated Countries[1] or part of the WHO prequalification program, therefore MSF is using a clear majority of products that are:

- CE mark according to 93/42/EC and 98/79/EC European Directives for MD and IVD respectively and/or
- USFDA cleared and/or
- In Vitro Diagnostics, male and female condoms and Intra-Uterine Devices prequalified by WHO

The manufacturer status against current ISO 13485 standard is verified.

The stringency of MSF assessment depends on the product classification. Please refer to Annex 1 and 2 for examples of classification for MD and IVD according to European Directives and US FDA classification rules and the corresponding MSF products of interest.

Besides the manufacturer's Declaration of Conformity (DoC), the CE and ISO 13485 certificates, for higher class risk products (class IIa, IIb, III and IVDs according to European regulation), the quality, safety and performance data are assessed via a product questionnaire, including the review of the labelling of secondary and primary packaging, testing reports, Instructions for Use and stability data where applicable.

In the rare case where no cleared product corresponding to MSF specific needs is available, MSF conducts manufacturer audits led by external auditors according to ISO 13485, in addition to an in-depth safety and performance data evaluation, a literature review and field tests if applicable.

The regulatory and quality product assessment is performed by MSF international 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.

2.3. **Vigilance system**

MSF has implemented procedures to fulfill the requirements of manufacturers' and suppliers' vigilance activities. Our SOP allow 1. MSF to collect the quality complaints from the field and report them to the legal manufacturers through the international procurement 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 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.

[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). 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.

Annex 1: Examples of classification for MDs according to Directive 93/42/EC[2] and US FDA classification rules and the corresponding MSF products of interest (not exhaustive)

EU	USA	Examples of medical devices (XXXX = MSF product nomenclature)
Class I	**Class I**	**Non sterile 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, MVA cannula and device, 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 gyneco gloves, amniohook 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 LP SDRE: fibrin sealant dressing, chitosan hemostatic dressing SMSU: IUD SSUT: absorbable sutures, non-absorbable mesh

[2] Classifications of MD and IVD will be updated according to EU 2017/745 (MDR) and EU 2017/746 (IVDR) in a later version of this document.

Annex 2: Classification of IVD according to the Directive 98/79/EC[3] and the corresponding MSF products of interest

Classifi-cation	IVD	Products of interest for MSF	
Annex II List A	Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell	Blood grouping tests (anti-A, anti-AB, anti B, Rhesus anti-D) RH negative control tests Bedside control cards for ABO compatibility	
	Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D; tests used to screen donated blood for vCJD	HIV 1 & 2 RDT HCV RDT HBV RDT	
Annex II List B	Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd	none	
	Reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies	none	
	Reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis	none	
	Reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria	none	
	Reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia	none	
	Reagents and reagent products, including related calibrators and control materials, for determining the following HLA tissue groups: DR, A, B	none	
	Reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: PSA	none	
	Reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21	none	
	The following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar	Blood glucose strips	
IVDs for self-testing	Excluding self-test IVDs covered in Annex II	Pregnancy RDT Reagents for CD4 automate	
General IVDs (Not A / not B)	Any IVD not identified in Annex II List A or List B or for self-testing	Tropical disease Malaria RDT Cholera RDT Cryptococcus RDT Leishmaniosis RDT Dengue RDT Meningitis RDT Trypanosomiasis RDT	Non tropical disease Syphilis RDT Rotavirus test Adenovirus test Biochemistry Urine strips

[3] Classifications of MD and IVD will be updated according to EU 2017/745 (MDR) and EU 2017/746 (IVDR) in a later version of this document.