[Letterhead of the Manufacturer]

Include company logo, full address, phone, email, and website

Medical Device details from the manufacturer

1.1 Name(s)

State the generic and brand name of the device.

1.2 Description

Provide a summary of information on design, characteristics and performance of the device. The description should also include information on device packaging.

1.3 Category

State the GMDN category of the device. If the device is not categorized according to GMDN and is coded based on other system, please specify.

1.4 Intended Use/Indication(s)

State the intended use(s) of the device and/or provide a general description of the disease or condition that the device will diagnose, treat, prevent, cure or mitigate. The description of the target patient population for which the device is intended should also be included. The statement of intended use should specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used and whether the device is intended for single use or multiple uses.

1.5 Instructions for Use

Give a concise summary of information for safe use of the device including procedures, methods, frequency, duration, quantity and preparation to be followed.

1.6 Contraindications

State conditions under which the device should not be used. The statement should specify the clinical conditions of a patient that would make use of the device inadvisable.

1.7 Warnings

State the specific hazard alert information that a user needs to know before using the device.

1.8 Precautions

State briefly precautions to be taken and any special care necessary for the safe and effective use of the device.

1.9 Adverse Effects

Describe all adverse and side effects associated with the device under normal conditions of use.

1.10 Alternative Use

Describe any alternative practices or procedures for diagnosing, treating, curing or mitigating the disease or condition for which the device is intended.

1.11 Storage conditions

State the storage conditions for the device. This should be based on results of stability studies conducted (where applicable).

1.12 Recommended shelf-life (where applicable)

State the recommended shelf-life of the device.

……..……
Name of the authorized Signatory:
Designation:
Company Seal: