



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document as below Annex. All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: HUBEI GUARDDENT MEDICAL TECHNOLOGY CO.,LTD
Address: Room 24-29th, 2/F, No.11 Block, No.1 Guiyuan Temple South Road, Hanyang District Wuhan City, China.
SRN: CN-MF-000028116

Product Information

PRODUCTS LIST IS ATTACHED BELLOW

Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that products listed in the annex meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2024.3.26

Position: GM  Place: Hubei/China

Annex

PRODUCT NAME	MODEL	EMDN	Basic UDI-DI	TECHNICAL DOCUMENT
IRRIGATION SYRINGES	1ml, 3ml, 5ml, 10ml, 12ml, 20ml,	Q010599	697565200IS001F6	Q010599-02
IRRIGATION NEEDLE	Notched, Side-vent, Double-vent,Pre-Bent 18GA,19GA,20GA. 21GA,22GA, 23GA, 25GA, 27GA, 30GA	Q010599	697565200IN001E3	Q010599-02
MICRO APPLICATORS	Regular, Fine, Superfine, Cylinder	Q010599	697565200MA001CL	Q010599-03
ABSORBENT PAPER POINT	02 taper, 04 taper,06 taper, F series Protaper	Q01010401	697565200APP001FA	Q01010401-01