



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-00000247

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: 2023
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Q01010401-01.

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 , 2nd Floor, No. 11 Block, No. 8
Yuanyang Dongfangjing Shijieguan, No.1 Guiyuan
Temple South Road, Hanyang District, Wuhan City,
Hubei Province, China
SRN: CN-MF-000028116

Product Information

Name: Absorbent Paper Point
Model: 02 taper, 04 taper,06 taper, F series Protaper
EMDN: Q01010401
Basic UDI-DI: 697565200APP001FA
Classification: Class I, According to Rule 5, Annex
VIII, Regulation (EU) 2017/745

Declaration

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

Signature: 

Date:2024.4.2

Position: GM

Place: Hubei/China

