



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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

Applicable Standards
EN ISO14971:2019
EN ISO15223-1:2016
ISO10993-1:2018
EN ISO10993-5:2009
EN ISO10993-10:2010
EN 1041:2008+A1:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-DB-03.

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.

合肥茂康卫生材料有限公司
HEFEI MLUSH SANITARY PRODUCTS CO.,LTD.

胡继奎

Manufacturer

Name: Hefei Mlush Sanitary Products Co., Ltd
Address: Room 612, Shengjing Building,463
Huangshan Rd, Shushan District, Hefei, Anhui,
China

Product Information

Name: DENTAL BIB
Model: 33cm*45cm or customized
GMDN: 61050
Basic UDI-DI: -
Classification: Class I, According to Rule 1, 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: 胡继奎 Date: 2021.6.22

Position: GM

Place: Anhui/China