

EU Declaration of Conformity

Manufacturer: Zhejiang Wellong Medical Technology Co., Ltd.
Lvshan Industrial area, Changxing County, 313105 Huzhou,
Zhejiang Province, China
SRN: CN-MF-000016084

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
SRN: DE-AR-000000001

Product Name: Sterile Non-woven Wound Dressing
Model: Model NW: 4X5, 5X7, 6X7, 7X8, 6X10, 8X10, 8X12, 9X10, 9X15,
9X20, 9X25, 9X30, 9X35, 10X10, 10X12.5, 10X15, 10X20,
10X25, 10X30, 10X35, 6X8IV, 6X8.3, 8X10IV, 10.2X10.2(cm)

EMDN Code: M04010101
Basic UDI-DI: 697309177SNWDSJ

Intended purpose of device: It is used to cover and protect the wound post-operation, cuts, lacerations and abrasions or be used for tube and I.V. set fixation.

Classification (MDR, Annex VIII): Class Is, Rule 1.

Conformity Assessment Route: Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above-mentioned products meet the provisions of the MDR (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Zhejiang Wellong Medical Technology Co., Ltd. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidances:

ISO 15223-1:2021, EN 1041:2008+A1:2013, EN ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, EN 13726-1:2002, EN 13726-2:2002, EN 62366-1-2015+AC:2015, EN ISO 14971:2019, ISO/TR 24971:2020, EN ISO 11607-1:2019, EN ISO 11607-2:2019, EN ISO 11737-1:2018, EN ISO 11737-2:2019, ISO 11135:2014+A2:2018, ASTM D4169-2016, MEDDEV. 2.7.1 Rev.4, MDCG 2020-6.

Notified Body: TÜV SÜD Product Service GmbH,
Ridlerstr. 65, 80339 München, Germany
NB Identification number: 0123
(EC) Certificate(s): G21 098235 0006 Rev. 00
Expire date of the Certificate: 2028-02-19
Start of CE Marking: 2023-02-20

Signature: 
Name: YING Jun
Position: General Manager
Place/date: Huzhou City, 2023-02-20