

Dongguan Tondaus Meditech Co.,Ltd.

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DECLARATION OF CONFORMITY TO REGULATION (EU) 2017/745

受控文件

MANUFACTURER : DONGGUAN TONDAUS MEDITECH CO., LTD.

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EUDAMED SRN: CN-MF-000023652

EC REPRESENTATIVE : Name: MedPath GmbH
Add: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
Tel: +49(0)89 189174474 E-mail: info@medpath.pro
EUDAMED SRN: DE-AR-000000087

UK REPRESENTATIVE : Name: Lotus Global Co., Ltd
Add: 23 Maine Street, Reading, RG2 6AG, England, United Kingdom.
Tel: 0044-20-70961611
E-mail: peter@lotusglobaluk.com

PRODUCT(S) : Surgical Skin Marker (Sterile)

PRODUCT CLASSIFICATION: Rule 1-CLASSIFICATION-ANNEX VIII-REGULATION (EU)2017/745 , Class I

CONFORMITY ASSESSMENT ROUTE: MDR (EU)2017/745 Annex XI Part A

Basic UDI-DI : 697180265 SSSM RJ

EMDN CODE: V9004

MODEL:

TR01、TR02、TR03、TR04、TF01、TF02、TF03、TF04、TD01、T3023、TS01、TS02、TS03;
EV01、EV02、EV03、EV04、EV05、EV06、EV07、EV08、EV09;
R01、R02、R03、R04、R05、R06、R07、R08、R09;
B01、B02、B03、B04、B05、B06、B07、B08、B09;
W01、W02、W03、W04;
D01、D02、D03、D04、D05、D06、D07、D08;
BV、RV、WV、DV、DB、DR、DW、DE;

WE HEREWITH DECLARE EXCLUSIVELY UNDER SOLE RESPONSIBILITY THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF REGULATION (EU)2017/745 FOR MEDICAL DEVICES. ALL THE PRODUCTS MEET THEIR INTENDED PURPOSE OF USE.

NOTIFIED BODY: TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich GERMANY

EC CERTIFICATE NO.: G15 103335 0004 Rev.00

IDENTIFICATION NUMBER: 0123

EXPIRY DATE OF EC CERTIFICATE: 2030-09-15

NAME: ELAINE LIU

SIGNATURE: 

POSITION: OVERSEA MARKET VICE DIRECTOR

ADDRESS: DONGGUAN, CHINA

DATE: 2025.09.17

