

Dongguan Tondaus Meditech Co., Ltd.

受控文件

TEL: +86-769-22987190 FAX: +86-769-27205312 Cell: +86 18819703898 E-Mail: s1@tondaus.com

DECLARATION OF CONFORMITY

MANUFACTURER : DONGGUAN TONDAUS MEDITECH CO., LTD.

ADDRESS : 3rd Floor, No.27, Rd. Guantai Chiling Community, Houjie Town
523900 Dongguan, Guangdong
PEOPLE'S REPUBLIC OF CHINA
Tel: +0769-22987270 Fax: +86-76927205312
E-mail: s1@tondaus.com

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

PRODUCT(S) : Surgical Skin Marker

PRODUCT CLASSIFICATION: Directive 93/42/EEC on Medical Devices (MDD) Annex IX, Class I (Sterile)

CONFORMITY ASSESSMENT ROUTE: MDD 93/42/EEC Annex V

EMDN CODE: V9004

Basic UDI-DI : 697180265 SSSM RJ

WE HEREWITH DECLARE EXCLUSIVELY UNDER SOLE RESPONSIBILITY THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES.

ALL THE PRODUCTS MEET THEIR INTENDED PURPOSE OF USE.

ALL THE EC FILES HAVE BEEN VALIDATED BY THIS MANUFACTURER AND THE NOTIFIED BODY AND WE ARE COMMITTED FOR THE AUTHENTICITY.

THE "SURGICAL SKIN MARKER" DEVICE BELONGS TO **CLASS I (STERILE)**

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

EC CERTIFICATE NO.: G2S 103335 0002 Rev. 00

IDENTIFICATION NUMBER: 0123

EXPIRY DATE OF EC CERTIFICATE: 31.12.2028

SIGNATURE:

NAME: Elvise

POSITION: Ovensen Manager Specialist

ADDRESS: DONGGUAN, CHINA

DATE: 24.04.2024



A3, 2024.04.24

Annex 1

受控文件

Model list

TR01, TR02, TR03, TR04, TF01, TF02, TF03, TD01, TS01, TS02, TS03,
TS05, T3023

