



EU DECLARATION OF CONFORMITY

Manufacturer:

Name: DISPOTECH SRL
Address: GORDONA (SO)- VIA AL PIANO, 29
VAT NUMBER: 00672170149
R.E.A.: 47213

SRN: IT-MF-000010735

DECLARES under its own responsibility that the product: NAPKINS

PRODUCT CODE: TO1ARAN, TO1ARGIMA, TO1BL, TO1BLGIMA, TO1LI, TO1LIAN, TO1LIGIMA, TO2AZ, TO2AZAN, TO2AZGIMA, TO2BI25LEAN, TO2BIAN, TO2BIGIMA, TO2RO, TO2ROAN, TO2ROGIMA, TO2VE, TO2VEAN, TO2VEGIMA

INTENDED PURPOSE: Patient protection device

BASIC UDI-DI: ++G066TODIS9B

satisfies all the general safety and performance requirements of REGULATION (UE) 2017/745 related to Medical Devices.

Class of Medical Device: I, annex VIII rule 1

In accordance with standard:

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
UNI CEI EN ISO 13485:2016 European harmonized standard for medical device quality management system
UNI CEI EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
UNI CEI EN ISO 14971:2020 Application of risk management to medical devices
UNI CEI EN 1041:2013 Information supplied by the manufacturer of medical devices
UNI EN ISO 10993-1:2021 Biological evaluation of medical devices
MEDDEV 2.7.1 rev.4 Clinical Evaluation: a guide for manufacturers and notified bodies

Place: Gordona

Legal Representative - Massimo Mortarotti
(responsible for the release of the product)

Date_31/01/2022_____

DISPOTECH S.R.L.
Via Al Piano, 29
23020 GORDONA (SO)
Tel. 0339 0343 36711 Fax 0339 36567
Codice Fiscale e Partita Iva 00672170149

Dispotech srl Via al piano, 29 23020 GORDONA (SO) Italia

Tel. +39 0343 36711 - Fax. +39 0343 36567 - e-mail: info@dispotech.it - www.dispotech.com

Cap Soc. € 1.500.000,00 i.v. - P. IVA 00672170149 - SDI BA6ET11 - R.E.A. 47213 C.C.I.A.A. di SO - Uff. Reg. Imp. SO 00672170149