



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: BIBS IN ROLL PERFECTO

PRODUCT CODE: MA1010PER, MA1012PER, MA1020PER, MA1022PER, MA1030PER, MA1032PER, MA1040PER, MA1042PER, MA1050PER, MA1052PER, MA1060PER, MA1062PER, MA1070PER, MA1072PER, MA1080PER, MA1082PER, MA1090PER, MA1092PER, MA2040PER, MA2042PER, MA2070PER, MA2072PER, MA2080PER, MA3020PER, MA3022PER, MA4030PER

INTENDED PURPOSE: Patient protection device

BASIC UDI-DI: ++G066MADIS3U

satisfies all requirements of REGULATION (UE) 2017/745 related to Medical Devices.

Class of Medical Device: I, annex VIII rule 1

In accordance with harmonized 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 13485:2021 European harmonized standard for medical device quality management system
UNI CEI EN ISO 15223-1:2021 Symbol to be used with medical device labels, labelling and information to be supplied
UNI CEI EN ISO 14971:2022 Application of risk management to medical devices
UNI CEI EN ISO 20417:2021 Information supplied by the manufacturer of medical devices
UNI EN ISO 10993-1:2021 Biological evaluation of medical devices
MEDDEV 2.7.1 Clinical Evaluation: a guide for manufacturers and notified bodies

Place: Gordona

Date_01/03/2023_____

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

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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