YOUR DISPOSABLE EXCELLENCE

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: EXAMINATION DRAPES IN ROLL

PRODUCT CODE: RUAZ505038P, RUBI505038P, RUBI605038C

INTENDED PURPOSE: Patient protection device

BASIC UDI–DI: ++G066RUDIS9X

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

Date_31/01/2022____

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

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