



DECLARATION OF COMPLIANCE



Manufacturer:

Name: DISPOTECH SRL
Address: CHIAVENNA (SO)- VIA MARIO DEL GROSSO, 8/12
VAT number: 00672170149
R.E.A.: 47213

DECLARES

under its own responsibility that the product: SALIVA EJECTOR DISPOEJECTOR

satisfies all the essential requirements as recommended in the Directive 93/42/EEC (Medical Devices) and successive modifications (included directive 2007/47/EC).

Classe of Medical Device: IIa enclosure IX rule 5

In accordance with harmonized standard:

European Directive 93/42/EEC and successive modifications (included European Directive 2007/47/EC)
MEDDEV 3/93-rev. 2 Guidelines on a medical devices vigilance system
UNI EN ISO 13485:2016 European harmonized standard for medical device quality management system
UNI CEI EN ISO 15223-1 "Symbol to be used with medical device labels, labelling and information to be supplied
UNI CEI EN ISO 14971:2012 Application of risk management to medical devices
UNI CEI EN 1041:2013 Information supplied by the manufacturer of medical devices
UNI EN ISO 10993-1:2010 Biological evaluation of medical devices
MEDDEV 2.7.1 Clinical Evaluation: a guide for manufacturers and notified bodies
European Pharmacopoeia (current edition)

CE certificate no.: 16679/1

Notified body no.: 0546 CERTIQUALITY SRL- Via Gaetano Giordano, 4- 20123 MILANO- ITALY

First issue: 22/03/2011

Current issue: 15/03/2016

Expiry date: 14/03/2021

Place: Gordona

Legal Representative
(responsible for the release of the product)

Date 26/08/2019



Dispotech srl

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