DECLARATION OF COMPLIANCE

Declaration of conformity of the product named DISPOPACK, made by the company DISPOTECH Ltd, to the necessary requirements quoted in the Enclosure I, Directive 93/42/EEC and successive modifications (Directive 2007/47/CE enclosed), as recommended in the Enclosure VII of the above mentioned directive and successive modifications.

The company DISPOTECH Ltd – Via Mario del Grosso 8/12, Chiavenna (SO) – manufacturing the product named DISPOPACK

DECLARES

under its own responsibility that the above mentioned product satisfies all the necessary requirements as recommended in the Directive 93/42/EEC (Medical Devices) and successive modifications.

The company DISPOTECH, moreover, declares and guarantees:

- The above mentioned product satisfies all the necessary requirements as recommended in the Enclosure I, Directive 93/42/EEC and successive modifications
- The above mentioned product belongs to Class I
- The above mentioned product is sold in NON STERILE packaging
- The above mentioned product IS NOT A DEVICE FOR MEASUREMENT
- The above mentioned product IS NOT INTENDED FOR CLINICAL INVESTIGATION

Being that the case, the manufacturer will set up an evaluation procedure on the experience so far acquired, as recommended in the enclosure VII-4 of the above mentioned Directive and successive modifications.

Technical documentation of the product is conserved in the offices of Dispotech srl Via al piano, 29 -23020 Gordona (SO)-

Technical documents will be available for the competent authority, for a period of five years from the last date of the manufacturing of the product, as recommended in the enclosure VII of the above mentioned Directive and successive modifications.

The manufacturer declares that the above mentioned product satisfies all the necessary requirements as recommended in the Directive 93/42/EEC and successive modifications, and that will be sold with CE mark, according to the Article 17- Directive 93/42/CEE and successive modifications.

Digitally signed by Palii Nina
Date: 2023.04.25 14:26:05 EEST
Reason: MoldSign Signature
Location: Moldova

Dispotech srl
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Sede legale: 23022 CHIAVENNA (SO) Via M. Del Grosso, 8/12 - e-mail: info@dispotech.it - www.dispotech.com
Cap Soc. € 100.000,00 i.v. - P. IVA 00672170149 - R.E.A. 47213 C.C.I.A.A. di SO - Uff. Reg. Imp. SO 00672170149

Others standards of reference:
European Directive 93/42/CEE and successive integrative modifications (es.: European Directive2007/47/CE)
Legislative Decree 24.02.1997, n.46
UNI CEI EN ISO 14971:2012 “Application of the administration of the dangers of medical dispositives”
UNI EN ISO 13485:2012 (“Medical dispositives–Systems of administration of quality – Conditions for regulation intent)”
UNI CEI EN ISO 15223-1 ed. 2012 “Symbols used for the labelling of medical dispositives”
UNI EN 1041:2009 (informations accomodated from the costumer of medical dispositives)
MEDDEV 3/93-rev. 2 Headlines about the system of vigilance of medical dispositives
UNI EN ISO 9001:2008 “System of administration for quality –conditions”
MEDDEV 2.7.1 Headlines about the clinical valutation of medical dispositives

04/08/2015

GENERAL MANAGER
(Massimo Mortarotti)

DISPOTECH S.r.l.
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