CHEMI-PHARM®

Chemi-Pharm AS Tänassilma tee 11, Tänassilma küla, Saku vald, Harju maakond 76406, Estonia Reg nr: 10140919 Tel: +372 6778606 chemi-pharm@chemi-pharm.com CERTIFIED BY

EC DECLARATION OF CONFORMITY

Council directive 2007/47/EC-revision of Directive 93/42/EEC.
About medical devices

We, CHEMI-PHARM AS, address Tänassilma tee 11, Tänassilma küla, Saku vald, Harju maakond 76406, Estonia, Republic of Estonia,
hereby declare in our sole responsibility , that product which is the subject of this declaration

1. Complies with the relevant requirements of council directive 2007/47/EC-revision of Medical Devices Directive 93/42/EEC. That the described medical product of risk class IIa:

Name of the product: STERISEPT wipes

Description: Fenol, aldehyde and phosphate free wipes for the cleaning and disinfecting of medical devices surfaces

Classification: Medical device belongs to hazard Class IIa, according to rule 15, Appendix IX of Council Directive 2007/47/EC-revision of Medical Devices Directive 93/42/EEC.

Procedure of attestation of conformity:

1. Conformity assessment for the medical device was performed according to appendix II of council 2007/47/EC-revision of Medical Devices Directive 93/42/EEC.
2. The management system conforms to the standards: EN ISO 13485:2016, ISO 9001:2015, ISO 14001:2015
3. The product conforms to the following standards EN ISO 14971:2012; EN 62366-2008; EN 1041:2008; ISO 15223-1:2016; EN 980:2008; EN ISO10993-1:2009/AC:2010; EN13704:2002; EN 14476:2013+A1:2015; EN 14348:2005; EN 13727:2012+A2:2015; EN 13624:2013; EN 14561:2006; EN 16615:2015; EN 13697:2015

Not applicable standards: Machinery Directive - 2006/42/EC, Pressure Equipment Directive - PED 2014/68/EEC and Personal Protective Equipment Directive 89/686/EEC

Notified Body : LRQA Nr 0088

Ruth Oltjer

Supervisor

Signature

Original approval:25.02.2010

Date 28.01.2019

Digitally signed by Margină Veaceslav
Date: 2019.05.28 14:49:45 EEST
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