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Date: 2025.11.12 13:58:37 EET
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MOLDOVA EUROPEANĂ

CHEMI-PHARM®

EC DECLARATION OF CONFORMITY

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

We, CHEMI-PHARM AS, address Tänassilma tee 11, Tänassilma küla, Saku vald, Harju maakond 76406, 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 device belongs to the risk class IIb:

Name of the product: STERISEPT INSTRU

Description: Aldehyde-free disinfection and cleaning agent for medical instruments satisfies the essential requirements of the directive 2007/47/EC-revision of Medical Devices Directive 93/42/EEC and therefore carries the CE marking of the European Union

Classification: Medical device belongs to hazard class IIb, according to rule 15, Appendix IX of Council Directive 2007/47/EC-revision of Medical Devices Directive 93/42/EEC regarding medical devices.

Procedure of attestation of conformity:

1. Conformity assessment for the medical device was performed according to appendix II of Council Directive 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. Not applicable standards: Machinery Directive – 2006/42/EC, Pressure Equipment Directive – PED 2014/68/EEC and Personal Protective Equipment Directive 89/686/EEC

The product conforms to the following standards: EN ISO14971:2012; EN 14885:2018; EN 62366:2008/A1:2015; EN 1041:2008/A1:2013; EN ISO10993-1:2009/AC:2010; EN ISO 15223-1:2016; EN13727:2012+A2:2015, EN13624:2013, EN14348:2005, EN14476:2013+A1:2015, EN 13704:2018, EN14561:2006;en14563:2008

Notified Body : Eurofins Expert Service CE0537

Ruth Oltjer

Chairwoman of the Board

Original approval: 30.04.2019
Updated: 19.08.2020