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: CHEMIDES PULVER

Description: medical device for high-level disinfection of reusable medical devices. Made of powder that releases peracetic acid in a solution. 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 by 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. Do not apply to Impact of Machinery Directive - 2006/42/EC, to Pressure Equipment Directive - PED 2014/68/EEC and to Personal Protective Equipment Directive 89/686/EEC

The product conforms to the following standards: EN ISO 14971:2012, EN 62366-2008/A1:2015, EN 1041:2008/A1:2013, EN ISO 15223-1:2016, EN ISO 10993-1:2009/AC:2010, EN 14885:2018; EN13727:2012+A2:2015, EN13624:2013,EN13697: 2015, EN14348:2005, EN14476:2013, EN14561:2006, EN14562:2006, EN14563:2009,EN13704:2002.

Notified Body : EUROFINS EXPERT SERVICES OY no.0537

Ruth Oltjer

Chairwoman of the Board

Sign

Digitally signed by Moraru Grigore
Date: 2025.11.12 14:00:06 EET
Reason: MoldSign Signature
Location: Moldova
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Original approval: 21.06.2006
Date: 19.08.2020

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