



EC DECLARATION OF CONFORMITY

This certifies that the following designated device

Product name: CTN X°Cryo™
Function: Localised cold treatment device, utilising electric compressor and heat exchanger technology.
Manufacturer: Cryotech Finland Oy Ltd
Address: CTN Center, Jaakonkatu 2, 01620 Vantaa, Finland

This declaration is to confirm that the above described device complies with the requirements of Directives listed below. This declaration has been issued on voluntary basis as devices of this class do not require certification from a notified body. We hereby certify that a Technical Construction File (TCF) is existent for the abovementioned product(s). This declaration applies to all devices manufactured in accordance with the TCF.

Assessment of compliance of the product was based on the following standards:

This product complies with the safety regulation of the EU directive as described in;

Low Voltage Directive 2006/95/EC
EMC Directive 2004/108/EC

and follows the European standards ;

EN 60335-1:2012
EN 55014-1:2006+A2:2011
EN 55014-2:1997+A2:2008
ISO 13485:2003

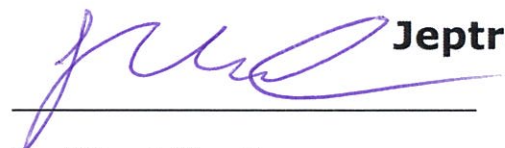
This declaration is the responsibility of the manufacturer

Cryotech Nordic AS


Juha Yliollitervo, Msc. Eng.
Technical Director



Inspected and verified by:


Jan Eklund, Msc. Eng.

Jeptron 

Date of issue: 15.10.2018 valid until 15.10.2023

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