TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60131579 0001

Report No.: 26300350 004

Manufacturer:
Cryo - Science Sp. z o.o.
ul. Logistyczna 4
55-040 Bielany Wroclawskie
Poland

Products:
- Local cryotherapy devices
- Whole-body cryotherapy chambers

Expiry Date: 2023-07-04

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-10-10

Date: 2018-10-10

Notified Body

D. Swiatko

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Cryo - Science Sp. z o.o.
ul. Logistyczna 4
55-040 Bielany Wroclawskie
Poland

has established and applies a quality management system for medical devices for the following scope:

Design and development, production, distribution, installation and servicing of medical devices for local and whole-body cryotherapy

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-10-10
Certificate Registration No.:	SX 60131580 0001
An audit was performed. Report No.:	26300350 004
This Certificate is valid until:	2021-07-04

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date 2018-10-10

D. Swiatko

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