TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60119069 0001

Report No.: 26300347 003

Manufacturer:
Kriomedpol Sp. z o.o.
ul. Warszawska 272
05-082 Stare Babice
Poland

Products:
- Cryotherapy devices for local cryostimulation
- Cryosurgery – tissue cryodestruction devices

Replaces EC Certificate, Registration No.: DD 60114289 0001

Expiry Date: 2021-09-06

The Notified Body hereby declares that the requirements of Annex V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-05-18

Date: 2017-05-18

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Sebastian Mniszek

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.