Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1370332-1

Organization: P.P.U. MEDBRYT Sp. z o.o.
ul. Cylichowska 3
04-769 Warszawa
Poland

Scope: Design and development, manufacturing, servicing and distribution of electrically powered nebulizers

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84950706 020

Effective date: 2020-11-20

Expiry date: 2023-10-03

Issue date: 2020-11-20

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Jarosław Pyclik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

EC Certificate

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

Registration No.: HD 60148562 0001

Report No.: 84944967 020

Manufacturer:
P.P.U. MEDBRYT Sp. z o.o.
ul. Cylichowska 3
04-769 Warszawa
Poland

Products:
- Compressor nebulizers
- Ultrasonic nebulizers

Replaces EC Certificate, Registration No.: HD 60142694 0001

Expiry Date: 2024-05-26

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: 2020-09-25

Date: 2020-09-25

Notified Body

Rafal Byczkowski

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.