

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

**Registration No.:** HD 60146440 0001

**Report No.:** 26300272 010

**Manufacturer:** INSTAL Technika Medyczna Sp. z o.o.  
ul. Mikołaja Reja 12  
35-211 Rzeszow  
Poland

**Products:** (see attachment for products included)

Replaces EC Certificate, Registration No.: HD 60099705 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:** 2020-02-08

**Date:** 2020-02-04



Notified Body

  
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.