

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60146440 0001
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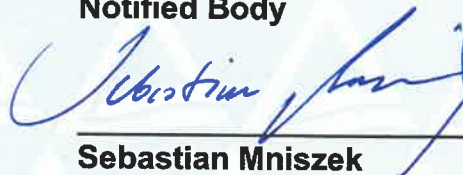
Manufacturer: INSTAL Technika Medyczna Sp. z o.o.
ul. Mikolaja Reja 12
35-211 Rzeszow
Poland

Products included:

- Terminal units for compressed medical gases and vacuum
- Medical supply units, wall mounted
- Medical gas flow regulators
- Shut-off valves
- Pressure regulation units for medical gas
- High pressure gas cylinder manifolds
- High pressure cooper pigtails
- High pressure flexible connecting tubes for gas cylinders
- Vacuum regulators
- Probes with valve for terminal units intended for use in medical gas pipeline systems
- Probes for terminal units intended for use in medical gas pipeline systems
- Medical gas pipeline installations
- Area shut-off valve, monitoring and alarm modules
- Monitoring and alarm panels for compressed medical gases and vacuum
- Shut-off valve modules
- Terminal units for anaesthetic gas scavenging systems

Date: 2020-02-04

Notified Body



Sebastian Mniszek

