

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

Registration No.: HD 60104808 0001

Report No.: 26300301 001

Manufacturer: BHH Mikromed Sp. z o.o.
ul. Katowicka 11
42-530 Dabrowa Gornicza
Poland

Products: See attachment for products included

Expiry Date: 2020-10-01

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: 2015-10-02

Date: 2015-10-02

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

**Attachment to
Certificate**

Registration No.: HD 60104808 0001
Report No.: 26300301 001

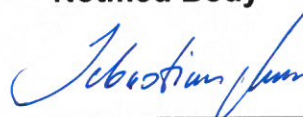
Manufacturer: BHH Mikromed Sp. z o.o.
ul. Katowicka 11
42-530 Dabrowa Gornicza
Poland

Products included:

- Non-sterile bone screws
- Non-sterile locking bone screws
- Non-sterile bone plates
- Non-sterile locking bone plates
- Non-sterile bone wires
- Non-sterile bone nails
- Non-sterile bone pins
- Non-sterile external fixators
- Non-sterile washers
- Non-sterile implants for intramedullary fixation
- Non-sterile bone drills
- Non-sterile bone screw taps
- Non-sterile bone cutters
- Non-sterile bone automatic screwdrivers

Date: 2015-10-02

Notified Body



Sebastian Mniszek

