

EC Certificate

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

Registration No.: HD 60145960 0001

Report No.: 28418348 002

Manufacturer: ADSM SAS

6 rue des Merisiers - les Erlen

68920 Wettolsheim

France

Products: - Sterile interphalangeal implants

- Sterile snap-off threaded pins

- Sterile snap-off Weil screws

- Sterile self-compressive cannulated screws

(see attachment for site included)

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:

2020-01-14

Date:

2020-01-14

Notified Body

Rafal Byczkowski

TÜVRheinlan

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. 1/1, Rev. 0

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Zinzierungss

Attachment to Certificate

Registration No.: Report No.:

HD 60145960 0001 28418348 002

Manufacturer:

ADSM SAS

6 rue des Merisiers - les Erlen

68920 Wettolsheim

France

Site included:

ADSM SAS 6 rue de Bretagne 38070 Saint Quentin Fallavier France

Activity: Design and development and manufacture.

Notified Body

Rafal Byczkowski

Date: 2020-01-14