

EC DESIGN-EXAMINATION CERTIFICATE

Number: 2194636DE02

Directive 93/42/EEC on Medical devices, Annex II (4)
(Devices in Class III)

Manufacturer:

Assut Medical Sarl
Av. de Rochettaz 57
1009 Pully
Switzerland

For the product

Temporary Pacing Wire made of multifilament steel (GMDN 45966)

Documents, that form the basis of this certificate:

Certification Notice 2194636CN, initially dated 20 September 2016
CE Marking of Conformity 2194636CE02

DEKRA hereby declares that the design of the product(s) falling within the product category mentioned above, fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments, based on an examination in accordance with Annex II (4) of this Directive. The manufacturer has implemented a quality assurance system for the above mentioned product category in accordance to the provisions of Annex II (4) of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance.

The necessary information and the reference to the relevant documentation, of the products concerned and the examinations and assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 2 October 2023
Issued for the first time: 23 September 2016
Reissued: 1 October 2018

DEKRA Certification B.V.

A blue ink signature of G.J. Zoetbrood, consisting of a stylized first name and a last name.

drs. G.J. Zoetbrood
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing initial 'J' and a clear last name.

J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

DEKRA Certification B.V. is Notified Body with ID no 0344

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