EC DESIGN-EXAMINATION CERTIFICATE

Number: 2126204DE03

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

Manufacturer:
PLAN 1 HEALTH S.R.L.
Via Solari 5
33020 Amaro (UD)
Italy

For the product

SecurePort Implantable Access Port System (Venous and Spinal) including Introducer Sets

Documents, that form the basis of this certificate:

Certification Notice 2126204CN, initially dated 4 August 2009
Addendum, initially dated 4 April 2016

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: 1 December 2022
Issued for the first time: 4 April 2016
Reissued: 15 January 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

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

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ADDENDUM

Belonging to certificate: 2126204DE03

EC DESIGN-EXAMINATION
MEDICAL DEVICES

SecurePort Implantable Access Port System (Venous and Spinal) including Introducer Sets

Issued to:

PLAN 1 HEALTH S.R.L.
Via Solari 5
33020 Amaro (UD)
Italy

This certificate covers the following product(s):

Model chambers:

LP
ETI
miniMax (Titanium)
Focus
Focus DC (Titanium and Polysulfon)
PLP
Power Ti
Power PLP

Initial date: 4 April 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
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