EC CERTIFICATE

Number: 2126204CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III and Devices in Class I in sterile conditions and sterilised systems or procedure packs)

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

For the product category(ies)
Implantable Access Systems and associated Introducer Sets, invasive Drug Delivery Devices for Administration of Pain Medication

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

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 above mentioned manufacturer 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. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection, that covers the aspects of manufacture concerned with securing and maintaining sterile conditions, for the above mentioned product category in accordance to the provisions of Annex II Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory.
The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the 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 August 2009
Reissued: 15 January 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

J.A. van Vugt
Certification Manager

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

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
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ADDENDUM

Belonging to certificate: 2126204CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Implantable Access Systems and associated Introducer Sets, invasive Drug Delivery Devices for Administration of Pain Medication

Issued to:

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

This certificate covers the following product(s):

- Implantable Access Port System (Venous and Spinal) (Class III)
- Implantable Central Venous Catheter System, peripherally inserted (Class III)
- Implantable Access Port System Arterial (Class IIb)
- PAINfusor Catheter (Class IIa)
- Accessories for Delivery Systems:
(includes Huber Needle with Extension Set, SecurePort Huber Needle with Extension Set, Huber Needle without Extension set, Huber Needle with Extension Set and Y-connector Site, Blunt tip Needle, HealthPort / HealthPicc Power Extension Set, Vein Lift, Openslide Clamp, Y-site) (Class IIa and Ist)
- Accessories for HealthPICC Catheter:
(includes Midline Mezzo, Nitinol Mandrel, Peel-Away Needle, HealthPicc Introducer Set) (Class IIa and Ist)

Initial date: 4 April 2016
Revision date: 13 September 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

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