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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 047402 0046 Rev. 01

Manufacturer: **Fresenius Kabi AG**
61346 Bad Homburg
GERMANY

Product: **Non-Active Implants**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713155539

Valid from: 2020-02-14
Valid until: 2024-05-26

Date, 2020-02-14

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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EC Certificate

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No. G7 047402 0046 Rev. 01

Facility(ies):

Clinico Medical Sp. z o.o. Blonie k / Wroclawia
ul. Roberta Kocha 1, 55-330 Blonie / Miekinia, POLAND

Model(s):

Implantable Port Catheter Systems and Accessories

Parameters:

Model-Nos. Model-Names:
8086001 Ambix Intraport® CP, venous
8086061 Ambix Intraport® CP, venous
8086071 Ambix Intraport® CP, venous
8086211 Ambix Intraport® C, venous
8086221 Ambix Intraport® C, venous
8086421 Ambix Intraport® T, paed., venous
8086431 Ambix Intraport® T, venous
8086441 Ambix Intraport® T, venous
8086461 Ambix Intraport® T, venous
8086012 Ambix Intraport® CP POWERFLOW, venous
8086442 Ambix Intraport® T POWERFLOW, venous

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