EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000005179)

PHS Medical GmbH

Ederweg 3
34277 Fuldabrück
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 3 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-05-24	Registration No.	D1069500034
Valid until:	2028-05-23	Evaluation Report No.	P22-00761-236641

Stuttgart, 2023-05-24

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
BS-MDR-098

Devices:

Product:
port systems: NuPort-CT, NuPort-LP-CT, C-Port

Intended purpose:
NuPort®/C-Port® port systems are subcutaneously implantable medical devices used when repeated access to the vascular system is indicated as part of therapy. These products provide the user with an easy-to-find site for cannula insertion to administer fluids, such as drugs, into the vascular system or to collect blood samples. The port is accessed by percutaneous puncture with a (non-coring) port cannula. The NuPort®/C-Port® port systems are available as standard vascular access ports, which are NOT suitable for high pressure injections, and as port systems for CECT high pressure injections. High pressure injections are performed using an appropriate infusion set with a non-coring port cannula. Port systems are intended for single use and are explanted and disposed of at the end of therapy.

Risk class: III
Basic-UDI-DI: 42503746PortsystemTitanNF

Product:
port systems: C-Port-CT, C-Port II

Intended purpose:
NuPort®/C-Port® port systems are subcutaneously implantable medical devices used when repeated access to the vascular system is indicated as part of therapy. These products provide the user with an easy-to-find site for cannula insertion to administer fluids, such as drugs, into the vascular system or to collect blood samples. The port is accessed by percutaneous puncture with a (non-coring) port cannula. The NuPort®/C-Port® port systems are available as standard vascular access ports, which are NOT suitable for high pressure injections, and as port systems for CECT high pressure injections. High pressure injections are performed using an appropriate infusion set with a non-coring port cannula. Port systems are intended for single use and are explanted and disposed of at the end of therapy.

Risk class: III
Basic-UDI-DI: 42503746PortsystemPSUC6

Product:
Percutaneous introducer set

Intended purpose:
The Introducer sets from PHS Medical GmbH are sterile accessories used exclusively for the insertion of the intravascular catheters included in the subcutaneously implantable port systems from PHS Medical GmbH. The product is used to assist the physician in implanting the PHS Medical port systems through a minimally invasive procedure known as the Seldinger technique.

Risk class: III
Basic-UDI-DI: 42503746IntroducerYF

Notes:

For the placing on the market of class III and IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors within the meaning of Regulation (EU) 2017/745, Art. 52 (4), 2nd paragraph and with the exception of custom-made devices of class III), an EU technical documentation assessment certificate is also required.