

EU Technical Documentation Assessment Certificate

We hereby certify that the company

PHS Medical GmbH
Ederweg 3
34277 Fuldabrück
Germany

has submitted a technical documentation in accordance with Annexes II and III of Regulation (EU) 2017/745, which meets the following requirements:

Annex IX – Chapter II (Assessment of the Technical Documentation)

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

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 6 pages. Details of the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2026-04-20
Valid until 2028-05-23

Registration No. D1069500038
Report No. P26-00241-356316

Stuttgart, 2026-04-20



Notified Body



Devices:

NuPort®-CT, standard, adult, venous, CECT-compatible, power injectable with and without Introducer:

NuPort-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter
NuPort-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter
NuPort-CT 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter
NuPort-CT 9F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter
NuPort-CT 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter
NuPort-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter and 50cm Guidewire
NuPort-CT 6.6F (PUR), Portsystem Set with 6.6F PUR-Catheter
NuPort-CT 7.5F (PUR), Portsystem Set with 7.5F PUR-Catheter
NuPort-CT 8F (Sil.), Portsystem Set with 8F Silicone-Catheter
NuPort-CT 9F (PUR), Portsystem Set with 9F PUR Catheter
NuPort-CT 9.6F (Sil.), Portsystem Set with 9.6F Silicone-Catheter

NuPort®-CT, standard, adult, venous, CECT-compatible, power injectable, left chest placement with and without Introducer:

NuPort-CT 6.6F (PUR), Portsystem incl. Introducer Set, left chest placement, with 6.6F PUR-Catheter
NuPort-CT 7.5F (PUR), Portsystem incl. Introducer Set, left chest placement, with 7.5F PUR-Catheter
NuPort-CT 8F (Sil.), Portsystem incl. Introducer Set, left chest placement, with 8F Silicone-Catheter
NuPort-CT 9F (PUR), Portsystem incl. Introducer Set, left chest placement, with 9F PUR-Catheter
NuPort-CT 9.6F (Sil.), Portsystem incl. Introducer Set, left chest placement, with 9.6F Silicone-Catheter
NuPort-CT 6.6F (PUR), Portsystem Set, left chest placement, with 6.6F PUR-Catheter
NuPort-CT 7.5F (PUR), Portsystem Set, left chest placement, with 7.5F PUR-Catheter
NuPort-CT 8F (Sil.), Portsystem Set, left chest placement, with 8F Silicone-Catheter
NuPort-CT 9F (PUR), Portsystem Set, left chest placement, with 9F PUR-Catheter
NuPort-CT 9.6F (Sil.), Portsystem Set, left chest placement, with 9.6F Silicone-Catheter

NuPort®-LP-CT, Low Profile/ArmPort, venous, CECT-compatible, power injectable with and without Introducer:

NuPort-LP-CT 5F (PUR), Portsystem incl. Introducer Set with 5F PUR-Catheter
NuPort-LP-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter
NuPort-LP-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter
NuPort-LP-CT 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter
NuPort-LP-CT 9F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter
NuPort-LP-CT 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter
NuPort-LP-CT 5F (PUR), Portsystem Set with 5F PUR-Catheter
NuPort-LP-CT 6.6F (PUR), Portsystem Set with 6.6F PUR-Catheter
NuPort-LP-CT 7.5F (PUR), Portsystem Set with 7.5F PUR-Catheter
NuPort-LP-CT 8F (Sil.), Portsystem Set with 8F Silicone-Catheter
NuPort-LP-CT 9F (PUR), Portsystem Set with 9F PUR-Catheter
NuPort-LP-CT 9.6F (Sil.), Portsystem Set with 9.6F Silicone-Catheter

PICC-NuPort®-CT, venous, CECT-compatible, power injectable with Introducer:

PICC-NuPort-CT 5F (PUR), Portsystem incl. Introducer Set with 5F PUR-Catheter
PICC-NuPort-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter

NuPort®-LP, Low Profile/ArmPort, venous with and without Introducer:
NuPort-LP 6F (Sil.), Portsystem incl. Introducer Set with 6F Silicone-Catheter
NuPort-LP 6F (Sil.), Portsystem Set with 6F Silicone-Catheter

C-Port®, standard, adult, venous with and without Introducer:
C-Port Standard 5F (PUR), Portsystem incl. Introducer Set with 5F PUR-Catheter
C-Port Standard 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter
C-Port Standard 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter
C-Port Standard 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter
C-Port Standard 9F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter
C-Port Standard 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter
C-Port Standard 5F (PUR), Portsystem Set with 5F PUR-Catheter
C-Port Standard 6.6F (PUR), Portsystem Set with 6.6F PUR-Catheter
C-Port Standard 7.5F (PUR), Portsystem Set with 7.5F PUR-Catheter
C-Port Standard 8F (Sil.), Portsystem Set with 8F Silicone-Catheter
C-Port Standard 9F (PUR), Portsystem Set with 9F PUR-Catheter
C-Port Standard 9.6F (Sil.), Portsystem Set with 9.6F Silicone-Catheter

NuPort® / NuPort®-CT / NuPort®-LP-CT / C-Port® Product Portfolio for Private Label Customers, standard, adult, venous with Introducer:

Fresenius C-Port 8F (Sil.), Portsystem incl. Introducer with 8F Silicone-Catheter
Fresenius C-Port 9.6F (Sil.), Portsystem incl. Introducer with 9.6F Silicone-Catheter
NuPort-HP 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter (Cardiva)
NuPort-HP 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter (Cardiva)
NuPort-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter (Cardiva)
NuPort-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter (Cardiva)
NuPort-LP-CT 5F (PUR), Portsystem incl. Introducer Set with 5F PUR-Catheter (Cardiva)
NuPort-LP-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter (Cardiva)
NuPort-LP-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter (Cardiva)

NuPort® / C-Port®, Custom Configurations with and without Introducer:
NuPort-CT 6.6F (PUR), Portsystem incl. Introducer Set with 47,3 cm 6.6F PUR-Catheter
NuPort-CT 7.5F (PUR), Portsystem incl. Introducer Set with 47,3 cm 7.5F PUR-Catheter
NuPort-CT 8F (Sil.), Portsystem incl. Introducer Set with 47,3 cm 8F Silicone-Catheter
NuPort-CT 9.0F (PUR), Portsystem incl. Introducer Set with 46,7 cm 9F PUR-Catheter
NuPort-CT 6.6F (PUR), Portsystem incl. Introducer Set, left chest placement, with 47,3 cm 6.6F PUR-Catheter
NuPort-CT 7.5F (PUR), Portsystem Set incl. Introducer Set, left chest placement, with 47,3 cm 7.5F PUR-Catheter
NuPort-LP 6.6F (PUR), Portsystem incl. Introducer Set with 47,3 cm 6.6F PUR-Catheter
NuPort-LP 7.5F (PUR), Portsystem incl. Introducer Set with 47,3 cm 7.5F PUR-Catheter
NuPort-LP 8F (Sil.), Portsystem incl. Introducer Set with 47,3 cm 8F Silicone-Catheter
NuPort-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter (Angiolux)
NuPort-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter (Angiolux)
NuPort-CT 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter (Angiolux)
NuPort-CT 9F (PUR), Portsystem incl. Introducer Set with 9F PUR Catheter (Angiolux)
NuPort-CT 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter (Angiolux)
NuPort-LP-CT 5F (PUR), Portsystem incl. Introducer Set with 5F PUR-Catheter (Angiolux)
NuPort-LP-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter (Angiolux)
NuPort-LP-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter (Angiolux)
NuPort-LP-CT 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter (Angiolux)
NuPort-LP-CT 9F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter (Angiolux)
NuPort-LP-CT 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter (Angiolux)
C-Port Standard 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter (Angiolux)

C-Port Standard 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter (Angiolux)
C-Port Standard 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter (Angiolux)
C-Port Standard 9F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter (Angiolux)
C-Port Standard 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter (Angiolux)
NuPort-CT 6.6F (PUR), Portsystem Set with 47,3 cm 6.6F PUR-Catheter
NuPort-CT 7.5F (PUR), Portsystem Set with 47,3 cm 7.5F PUR-Catheter
NuPort-CT 9.0F (PUR), Portsystem Set with 46,7 cm 9F PUR-Catheter
NuPort-CT 6.6F (PUR), Portsystem Set, left chest placement, with 47,3 cm 6.6F PUR-Catheter
NuPort-CT 7.5F (PUR), Portsystem Set, left chest placement, with 47,3 cm 7.5F PUR-Catheter
NuPort-LP 6.6F (PUR), Portsystem Set with 47,3cm 6.6F PUR-Catheter
NuPort-LP 7.5F (PUR), Portsystem Set with 47,3 cm 7.5F PUR-Catheter
NuPort-LP 8F (Sil.), Portsystem Set with 47,3 cm 8F Silicone-Catheter

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

C-Port®-CT, standard, adult, venous, CECT-compatible, power injectable, [lila] with and without Introducer:

C-Port-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter
C-Port-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter
C-Port-CT 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter
C-Port-CT 9F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter
C-Port-CT 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter
C-Port-CT 6.6F (PUR), Portsystem Set with 6.6F PUR-Catheter
C-Port-CT 7.5F (PUR), Portsystem Set with 7.5F PUR-Catheter
C-Port-CT 8F (Sil.), Portsystem Set with 8F Silicone-Catheter
C-Port-CT 9F (PUR), Portsystem Set with 9F PUR-Catheter
C-Port-CT 9.6F (Sil.), Portsystem Set with 9.6F Silicone-Catheter

C-Port®-II, standard, adult, venous [natural] with and without Introducer:

C-Port-II 5F (PUR), Portsystem incl. Introducer Set with 5F PUR-Catheter
C-Port-II 6F (Sil.), Portsystem incl. Introducer Set with 6F Silicone-Catheter
C-Port-II 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter
C-Port-II 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter
C-Port-II 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter
C-Port-II 9F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter
C-Port-II 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter
C-Port-II 5F (PUR), Portsystem Set with 5F PUR-Catheter
C-Port-II 6F (Sil.), Portsystem Set with 6F Silicone-Catheter
C-Port-II 6.6F (PUR), Portsystem Set with 6.6F PUR-Catheter
C-Port-II 7.5F (PUR), Portsystem Set with 7.5F PUR-Catheter
C-Port-II 8F (Sil.), Portsystem Set with 8F Silicone-Catheter
C-Port-II 9F (PUR), Portsystem Set with 9F PUR-Catheter
C-Port-II 9.6F (Sil.), Portsystem Set with 9.6F Silicone-Catheter

C-Port®-CT, Product Portfolio for Private Label Customers, standard, adult, venous with Introducer:

C-Port-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter (Cardiva)
C-Port-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter (Cardiva)
C-Port-CT 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter (Cardiva)
C-Port-CT 9F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter (Cardiva)
C-Port-CT 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter (Cardiva)

C-Port®-CT + C-Port®-II, Custom Configuration with and without Introducer:

C-Port-CT 6.6F (PUR), Portsystem incl. Introducer Set with 47,3 cm 6.6F PUR-Catheter
C-Port-CT 7.5F (PUR), Portsystem incl. Introducer Set with 47,3 cm 7.5F PUR-Catheter
C-Port-CT 8F (Sil.), Portsystem incl. Introducer Set with 47,3 cm 8F Silicone-Catheter
C-Port-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter (Angiolux)
C-Port-CT 7.5F (PUR), Portsystem incl. Introducer Set with 7.5F PUR-Catheter (Angiolux)
C-Port-CT 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter (Angiolux)
C-Port-CT 9.0F (PUR), Portsystem incl. Introducer Set with 9F PUR-Catheter (Angiolux)
C-Port-CT 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter (Angiolux)
C-Port-II 8F (Sil.), Portsystem incl. Introducer Set with 8F Silicone-Catheter (Angiolux)
C-Port-II 9.6F (Sil.), Portsystem incl. Introducer Set with 9.6F Silicone-Catheter (Angiolux)
C-Port-CT 6.6F (PUR), Portsystem Set with 47,3 cm 6.6F PUR-Catheter
C-Port-CT 7.5F (PUR), Portsystem Set with 47,3 cm 7.5F PUR-Catheter

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

Percutaneous Introducer Set:

Percutaneous introducer set 6F (compatible with PHS Medical NuPort/C-Port with 5F catheters)
Percutaneous introducer set 7F (compatible with PHS Medical NuPort/C-Port with 6F & 6.6F catheters)
Percutaneous introducer set 8F (compatible with PHS Medical NuPort/C-Port with 7.5F catheters)
Percutaneous introducer set 9F (compatible with PHS Medical NuPort/C-Port with 7.5F & 8F catheters)
Percutaneous introducer set 10F (compatible with PHS Medical NuPort/C-Port with 9F & 9.6F catheters)
Percutaneous introducer set - Micropuncture Set 5.5F (compatible with PHS Medical NuPort/C-Port with 5F catheters)
Percutaneous introducer set - Micropuncture Set 7F (compatible with PHS Medical NuPort/C-Port with 6.6F catheters)

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 the devices an EU Quality Management System Certificate according to Annex IX, Chapter I of Regulation (EU) 2017/745 on medical devices is also required.

The certificate is based on the previous certificate

D1069500035 (2023-05-24)

with the following changes to D1069500035:

Supplemented by the following products:

- PICC-NuPort-CT 5F (PUR), Portsystem incl. Introducer Set with 5F PUR-Catheter
- PICC-NuPort-CT 6.6F (PUR), Portsystem incl. Introducer Set with 6.6F PUR-Catheter
- Percutaneous introducer set - Micropuncture Set 5.5F (compatible with PHS Medical NuPort/C-Port with 5F catheters)
- Percutaneous introducer set - Micropuncture Set 7F (compatible with PHS Medical NuPort/C-Port with 6.6F catheters)

and listing of all variants