



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 114689 0001 Rev. 00

Manufacturer:

PYTHEAS NAVIGATION SAS

52 rue Emmanuel Eydoux
13016 Marseille
FRANCE

SRN Manufacturer - FR-MF-000003451

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 114689 0001 Rev. 00

Report No.:

ITA1774736

Valid from:

2023-10-16

Valid until:

2028-10-15

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2023-10-16



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Classification: Class IIb
Device Group: Z120114 - SURGICAL NAVIGATION INSTRUMENTS
Intended Purpose: Aid for use in open pedicle cannulation and screw delivery procedures in the thoracic, lumbar and sacral spine in skeletally mature patients as an augment to standard surgical technique. When used in conjunction with preoperative CT imaging, the system provides angular guidance to the surgeon for assessing the angle of approach relative to patient spinal anatomy.

The validity of this certificate \
depends on conditions and/or
is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2023-10-16	ITA1774736	Initial issuance