

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 789298 R000

Manufacturer: Norav Medical GmbH

Address:

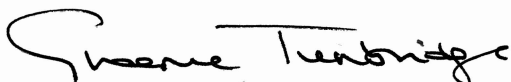
Christof-Ruthof-Weg 10
55252 Mainz-Kastel
Germany

Single Registration Number: DE-MF-000006715

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-04-03**

Current Issue Date: **2025-04-03**

Starting Validity Date: **2025-04-03**

Expiry Date: **2030-04-02**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 789298 R000

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Cardiography systems including associated software	Class IIa



First Issue Date: **2025-04-03**

Current Issue Date: **2025-04-03**

Starting Validity Date: **2025-04-03**

Expiry Date: **2030-04-02**

...making excellence a habit.™

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 789298 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3911806	Issued

First Issue Date: **2025-04-03**

Current Issue Date: **2025-04-03**

Starting Validity Date: **2025-04-03**

Expiry Date: **2030-04-02**

...making excellence a habit.™