

# EU Quality Management System Certificate

We hereby certify the company

**Dr. Sennewald Medizintechnik GmbH**  
**Schatzbogen 86**  
**81829 München**  
**Germany**

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets 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 from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2024-07-23  
Valid until 2029-06-15

Registration No. D1367500009  
Report No. P23-00551-265595

Stuttgart, 2024-07-23



Notified Body



## Devices:

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### SigmaVision Advanced

Intended purpose: The SigmaVision Advanced software system displays temperature differences within the body on the basis of MRI slice images.

The temperature differences are displayed to the user at regular intervals, usually 10-15 minutes, during the hybrid hyperthermia treatment.

Risk class: IIb

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