

# Certificate

We hereby certify the company

**NDI Europe GmbH  
Güttinger Straße 37  
78315 Radolfzell  
Germany**

with the sites listed in the attachment the introduction and application of a

## Quality management system according to EN ISO 13485

in the scope

Design and development, manufacturing, distribution and repair of electromagnetic 3D position measuring systems suitable for integration into medical systems;

Distribution of optical 3D position measuring systems suitable for integration into medical systems;

Authorized Representative, Importer and Distributor in the EU for sterile marker spheres as accessories for the optical position measuring systems

An audit by mdc has proven that this quality management system meets the requirements of the following standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016

Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2025-10-07  
Valid until 2028-10-06

Registration No. D1298800005  
Report No. P25-00471-330363

Stuttgart, 2025-10-02



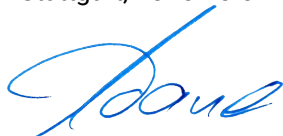
Certification Body



## Sites included in the certification:

| Location                                                              | Scope                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NDI Europe GmbH<br>Güttinger Straße 37<br>78315 Radolfzell<br>Germany | Design and development, manufacturing, distribution and repair of electromagnetic 3D position measuring systems suitable for integration into medical systems;<br>Distribution of optical 3D position measuring systems suitable for integration into medical systems;<br>Authorized Representative, Importer and Distributor in the EU for sterile marker spheres as accessories for the optical position measuring systems |
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Certification Body