



CERTIFICATE

Quality Management System Certificate EN-ISO 13485:2016

The certificate: 23M00189CRT01

issued by: **Kiwa Dare B.V.**
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands

to:
Manufacturer Intelligent Ultrasound Limited
Address Hodge House 114-116 St Mary Street
CF10 1DY, Cardiff
United Kingdom

Tradenames: Medaphor Limited and Intelligent Ultrasound Limited are subsidiaries of Intelligent Ultrasound Group Plc

Regarding the scope: The design and development, manufacture, installation, distribution of Medical image processing software and associated hardware for the area of ultrasound imaging

This certificate is based on the following documents:
23M00184PRP01

Kiwa Dare B.V. hereby declares that it has audited the quality management system in accordance with EN-ISO 13485:2016 + AC:2018 + A11:2021 and that all requirements of the standard and its implementation are fulfilled.

The validity of this certificate is three years and includes the surveillance obligations of EN-ISO 17021-1:2015.

Issued for the first time: 08-Apr-2021
Reissued: 21-Apr-2021
Re-certification: 08-Apr-2024
Valid to: 08-Apr-2027

Kiwa Dare B.V.

DocuSigned by:
Natascha Cuper
6B5E3A6BE84046A...

Dr. N. Cuper
Certification decision maker

DocuSigned by:
Dennis van der Vlugt
4F831C843C0B4EA...

Ing. D. Van der Vlugt
Director





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Appendix of EN-ISO 13485 Certificate

Certified additional locations and/or organizations	Scope
Medaphor Limited Unit 22, Trecenydd Business Park, CF83 2RZ, Caerphilly United Kingdom	The design and development, manufacture, installation, distribution of Medical image processing software and associated hardware for the area of ultrasound imaging

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