

Quality Management System Certificate EN-ISO 13485:2016

The certificate : 21M00049CRT04

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

to:
Manufacturer : Intelligent Ultrasound Limited
Address, Main site : Intelligent Ultrasound Limited, Hodge House 114-116 St Mary Street CF10 1DY, Cardiff, United Kingdom
Activities : Design, development and customer-related processes
Address, additional site : Medaphor Limited, Unit 22, Trecenydd Business Park, CF83 2RZ, Caerphilly, United Kingdom
Activities : Production, packaging, labelling, shipping, installation, feedback and complaint handling
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:

20M00066RPT02

Kiwa Dare B.V. hereby declares that it has audited the quality management system in accordance with EN-ISO 13485:2016 + AC:2018 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 April 2021
Reissued: 21 April 2021
Valid to: 08 April 2024

Kiwa Dare B.V.



Dr. Ir. W. Sjoerdsma
Certification decision maker



Ing. D. Van der Vlugt
Director

Certificate number: 21M00049CRT04