

CERTIFICATE

EU Quality Management System Certificate – Annex IX Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation Regulation 2017/745 on MEDICAL DEVICES

The certificate: 20M00084CRT01

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

to:
Manufacturer iSMART Development Ltd.
Address 129 Greens Lanes, Sutton Coldfield
B74 5LT Birmingham
England

SRN: GB-MF-000020855

EAR: Med-Di-Dia Limited
Galway Technology Centre, Mervue Business
Park H91 D932 Galway
Ireland
IE-AR-000003996

The scope of certificate comprises an EU quality management system regarding the following devices or groups of devices: Active non-implantable devices utilizing non-ionizing radiation

This certificate is based on the following documents:

Audit report: 20M00084PRP03
TD report: 21M00131RPT01

Kiwa Dare B.V. hereby declares that it has audited the quality assurance system in accordance with MDR Annex IX and that the relevant provisions of the Regulation 2017/745 dated May 5, 2017 concerning Medical Devices are fulfilled. The validity of this certificate is five years and includes the surveillance obligations of Annex IX, section 3. The products shown in the scope of certification are covered by this certificate and may bear the CE marking using the Notified Body number "1912".

Issued for the first time: 09-03-2023
Reissued: NA
Valid to: 09-03-2028

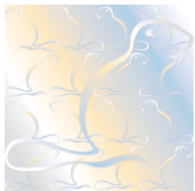
Preceding certificates: NA

**Date of identification
of changes:** NA

Kiwa Dare B.V.

Dr. Ir. W. Sjoerdsma
Certification decision maker

Ing. D. Van der Vlugt
Director



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Appendix of EU Quality Management System Certificate – Annex IX

Devices/groups of devices	Risk classification	Intended purpose (only IIb and III)
Omnilux CLEAR Acne Facemask MDA0302 Active non-implantable devices utilizing non-ionizing radiation	Devices in Class IIa	-

The certificate: **20M00084CRT01**

The facilities covered by this certificate are:

iSMART Development Ltd.
129 Greens Lanes, Sutton Coldfield
B74 5LT Birmingham
England