EU Quality Management System Certificate KR23/00000139

The management system of

Medios Co., Ltd.

126, Techno 2-ro, Yuseong-gu, Daejeon, 34029, Republic of Korea
SRN Number: KR-MF-000011624

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

Class IIa

MDN1206, MDS 1005

Sterile Soft Contact Lens (Model: Cube-I 38 - Basic UDI-DI: 88061529CUBEI38QH)
Sterile Soft Colored Contact Lens (Model: Hi-Color 58 - Basic UDI-DI: 88061529HICOLOR58MC)

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation:
N/A

Certification is based on following reports: WW/PCI/216481 - S2A 2.0

Authorized representative Name and address (if relevant): KTR Europe GmbH, Mergenthalerallee 77, 65760 Eschborn, Germany

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 31 August 2023 until 31 August 2028 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 February 2028

Issue 1. Certified since 31 August 2023

Authorised by
Virginie Siloret
Global Medical Device Certification Manager

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