EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Consol AB

Krokslättsgatan 7, SE-431 67 Mölndal, Sweden

Manufacturer SRN: SE-MF-000000010

Scope:

Contact Lens care solutions

Certificate Number:
28620163217

Revision:
00

Initial Certification Date:
20 December 2023

Certificate Decision Date:
20 December 2023

Certificate Issue Date:
20 December 2023

Certificate Expiry Date:
19 December 2028

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00285-01 Consol AB EXTEND Contact Lens Solution**
Audit Report Reference	**Stage 1 audit ACTY-2022-607267**
	Stage 2 audit ACTY-2022-607268

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620163217

Revision:
00

Initial Certification Date:
20 December 2023

Certificate Decision Date:
20 December 2023

Certificate Issue Date:
20 December 2023

Certificate Expiry Date:
19 December 2028

Mikael Hagelin
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

MDR – Decision Report

Certificate No: 28620163217
Date: 20 December 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Consol AB
Attn: Jan Johnsson
Krokslättsgatan 7
SE-431 67 Mölndal
Sweden

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2022-607267	Mölndal, Sweden	Daniel Malica	27 – 28 Apr 2023
Stage 2 ACTY-2022-607268	Mölndal, Sweden	Daniel Malica	27 – 30 June 2023

Technical Documentation Report	Assessor Name	Assessment Date
2023-12-20 TD Assessment Report ConsolAB TD000285-01_Final_TD00285-01	James Glaisher	20 December 2023
2023-12-20 CEAR ConsolAB EXTEND_TD00285-01-Final_TD00285-01	James Glaisher	20 December 2023
2023-12-20 TD Non-Conformities Consol AB_TD00285-01_TD00285-01	James Glaisher	20 December 2023
2023-12-20 TD Non-Conformities Consol AB_TD00285-01_TD00285-01	James Glaisher	20 December 2023

Scope of assessment

Contact Lens care solutions, Class IIb

Result

0 non conformitiy were noted during the audit.

All non-conformities noted during the technical documentation assessment(s) have been closed.

Certificate Type

EU Quality Assurance Certificate

Certificate Valid from

20 December 2023

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

Appeals

Any appeal against this decision will be processed by an appeals panel

as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Lian Zhang
Certification Authority (TD Assessment)

Mikael Hagelin
Certification Authority (Audit)