

# 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



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

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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.

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**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
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**CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

**Certificate Number:**  
28620163217

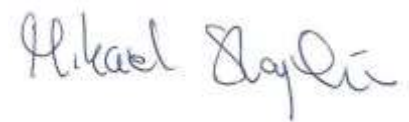
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Certificate No: 28620163217  
Date: 20 December 2023  
Handled by: Caroline Åman  
E-mail: IMNB@intertek.com

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

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

<b>Activity</b>	<b>Audit Type</b>	<b>Location</b>	<b>Auditor Name</b>	<b>Audit Date</b>
	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

<b>Technical Documentation Report</b>	<b>Assessor Name</b>	<b>Assessment Date</b>
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 conformity 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)