EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 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 restricted to the aspects relating to the conformity of the devices with metrological requirements - 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.

Certificate Number:
28620170638

Revision:
00

Initial Certification Date:
21 March 2024

Date of Certification Decision:
21 March 2024

Certificate Issue Date:
21 March 2024

Certificate Expiry Date:
29 December 2028

Graphic Controls Acquisition Corp

400 Exchange St, Buffalo, New York 14204, United States

Manufacturer SRN: US-MF-000012773

Authorised Representative Name
NISSHA MEDICAL TECHNOLOGIES SAS
Boulevard de la Paix, 23-25 95800 Cergy, France

Scope:

Metrology aspects of devices as detailed in attached product list.

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

Last Audit report reference	**Stage 1 audit ACTY-2019-390377**
	Stage 2 audit ACTY-2023-065925

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620170638

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MDR – Decision Report

Certificate No: 28620170638
Date: 21 March 2024
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Graphic Controls Acquisition Corp
Attn: Juliana Scotto di Carlo
400 Exchange St
Buffalo, New York 14204
United States

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
Expiry date on MDR certificate is set to be aligned with client´s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2019-390377	New York	Levent Durukan, Brian Dougherty, Mihaela Ungur	14 – 17 Nov 2023
Stage 2 ACTY-2023-065925	New York	Levent Durukan	7 – 9 Feb 2024

Scope of assessment

Metrology aspects of devices as detailed in attached product list, Class 1(m)

Result

0 non conformitiy were noted during the audit.

Certificate Type

EU Quality Assurance Certificate

Certificate Valid from

21 March 2024

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

Mikael Hagelin
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: Graphic Controls Acquisition Corp

Certificate number: 28620170638

Certificate valid from: 2024-03-21

Product List Issue Date:
11 April 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Class I Measuring Device			
Basic UDI-DI: 009336Measuring-Chart72			
7G01082320 - LTN 781-080-12	Class I(m) Z1302		2024-03-21
7G10005156 - HP 9270-0484	Class I(m) Z1302		2024-03-21
7G10643709 - HP 9270-0485	Class I(m) Z1302		2024-03-21
7G30589132 - CMS 4483	Class I(m) Z1302		2024-03-21
7G30597226 - CMS 4305 (40/CA)	Class I(m) Z1302		2024-03-21
7G30748696 - HP M1910A (40/CA)	Class I(m) Z1302		2024-03-21
7G30767589 - CMS 4305 BAO	Class I(m) Z1302		2024-03-21
7G30791761 - HP M1913A	Class I(m) Z1302		2024-03-21
7G32016831 - HP M1911A (40/CA)	Class I(m) Z1302		2024-03-21
7G32020410 - MRN 9100-025-50	Class I(m) Z1302		2024-03-21
7G32020618 - EDN CADENCE (MS1-01921)	Class I(m) Z1302		2024-03-21
7G32021183 - HP M1911A (ARCHIVAL/25YR)	Class I(m) Z1302		2024-03-21
7G32024151 - SPA AMS-31-0427	Class I(m) Z1302		2024-03-21
7G32024161 - EDN F6/F9	Class I(m) Z1302		2024-03-21
7G32024300 - SPA AMS-31-0432	Class I(m) Z1302		2024-03-21
Basic UDI-DI: 009336Measuring-ChartGKS			
2104907-00 - GEH 2104907-001	Class I(m) Z1302		2024-03-21

[1] The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
2104908-001 - GEH 2104908-001	Class I(m) Z1302		2024-03-21
32029833 - GEH 5818864	Class I(m) Z1302		2025-04-11
Basic UDI-DI: 009336Measuring-ChartVLQ			
2009828-CAO - VYR 2009828-CAO	Class I(m) Z1302		2024-03-21
2009828-DAO - VYR 2009828-DAO	Class I(m) Z1302		2024-03-21
2009828-FAO - VYR 2009828-FAO	Class I(m) Z1302		2024-03-21

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

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620170638
Product list issue date: 11 April 2025