# 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

**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

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: 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:**
21 March 2024

| 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)<br>Z1302 | | 2024-03-21 |
| 7G10005156 - HP 9270-0484 | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G10643709 - HP 9270-0485 | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G30589132 - CMS 4483 | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G30597226 - CMS 4305 (40/CA) | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G30748696 - HP M1910A (40/CA) | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G30767589 - CMS 4305 BAO | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G30791761 - HP M1913A | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G32016831 - HP M1911A (40/CA) | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G32020410 - MRN 9100-025-50 | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G32020618 - EDN CADENCE (MS1-01921) | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G32021183 - HP M1911A (ARCHIVAL/25YR) | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G32024151 - SPA AMS-31-0427 | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G32024161 - EDN F6/F9 | Class I(m)<br>Z1302 | | 2024-03-21 |
| 7G32024300 - SPA AMS-31-0432 | Class I(m)<br>Z1302 | | 2024-03-21 |
| ***Basic UDI-DI: 009336Measuring-ChartGKS*** | | | |
| 2104907-00 - GEH 2104907-001 | Class I(m)<br>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)<br>Z1302 | | 2024-03-21 |
| ***Basic UDI-DI: 009336Measuring-ChartVLQ*** | | | |
| 2009828-CAO - VYR 2009828-CAO | Class I(m)<br>Z1302 | | 2024-03-21 |
| 2009828-DAO - VYR 2009828-DAO | Class I(m)<br>Z1302 | | 2024-03-21 |
| 2009828-FAO - VYR 2009828-FAO | Class I(m)<br>Z1302 | | 2024-03-21 |

**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.

[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:* 21 March 2024