UKCA CERTIFICATE

PRODUCTION QUALITY ASSURANCE

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

We hereby declare that an examination of the under mentioned production quality assurance system restricted to the aspects of manufacture concerned metrological requirements has been carried out following the requirements of UK Statutory Instrument 2002 No. 618, as amended, to which the undersigned is subjected.

We certify that the production quality assurance system conforms with the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the UKCA 8532 marking on those products listed below.

Graphic Controls Acquisition Corp

400 Exchange St
Buffalo, New York 14204
United States

Scope:

Class I devices with a measuring function

For further identification of the products covered, see the attached product list/product schedule

Certificate Number:
85320192511

Revision:
00

Initial Certification Date:
26 September 2024

Date of Certification Decision:
26 September 2024

Certificate Valid Date:
26 September 2024

Certificate Expiry Date:
29 December 2028

Sharmila Gardner
Head of UK Approved Body
Intertek Medical Notified Body UK Ltd
Academy Place, 1-9 Brook Street
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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the UK Approved Body.

Intertek Medical Notified Body UK Ltd is a UK Approved Body according to UK SI 2002 No. 618 on medical devices, with identification number 8532.

PRODUCT LIST FOR CERTIFICATE

Issued to: Graphic Controls Acquisition Corp

Certificate number: 85320192511

Certificate valid from: 2024-09-26

Product List Issue Date:
11 April 2025

Product	Classification and GMDN	Intended use[1]	Date Added
Class I Measuring Device			
Basic UDI-DI: 009336Measuring-Chart72			
7G01082320 - LTN 781-080-12	Class I(m) 61901		2024-03-21
7G10005156 - HP 9270-0484	Class I(m) 61901		2024-03-21
7G10643709 - HP 9270-0485	Class I(m) 61901		2024-03-21
7G30589132 - CMS 4483	Class I(m) 61901		2024-03-21
7G30597226 - CMS 4305 (40/CA)	Class I(m) 61901		2024-03-21
7G30748696 - HP M1910A (40/CA)	Class I(m) 61901		2024-03-21
7G30767589 - CMS 4305 BAO	Class I(m) 61901		2024-03-21
7G30791761 - HP M1913A	Class I(m) 61901		2024-03-21
7G32016831 - HP M1911A (40/CA)	Class I(m) 61901		2024-03-21
7G32020410 - MRN 9100-025-50	Class I(m) 61901		2024-03-21
7G32020618 - EDN CADENCE (MS1-01921)	Class I(m) 61901		2024-03-21
7G32021183 - HP M1911A (ARCHIVAL/25YR)	Class I(m) 61901		2024-03-21
7G32024151 - SPA AMS-31-0427	Class I(m) 61901		2024-03-21
7G32024161 - EDN F6/F9	Class I(m) 61901		2024-03-21
7G32024300 - SPA AMS-31-0432	Class I(m) 61901		2024-03-21
Basic UDI-DI: 009336Measuring-ChartGKS			
2104907-00 - GEH 2104907-001	Class I(m) 61901		2024-03-21

[1]The intended use is only included for Class IIb and class III devices

Product	Classification and GMDN	Intended use	Date Added
2104908-001 - GEH 2104908-001	Class I(m) 61901		2024-03-21
32029833 - GEH 5818864	Class I(m) 61901		2025-04-11
Basic UDI-DI: 009336Measuring-ChartVLQ			
2009828-CAO - VYR 2009828-CAO	Class I(m) **6**1901		2024-03-21
2009828-DAO - VYR 2009828-DAO	Class I(m) **6**1901		2024-03-21
2009828-FAO - VYR 2009828-FAO	Class I(m) **6**1901		2024-03-21

Sharmila Gardner
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Brentwood, Essex
CM14 5 NQ United Kingdom

Intertek Medical Notified Body UK Ltd is an Approved Body in accordance with the requirements set out in IK Statutory Instruments 2002 No. 618 on Medical Devices, with the identification number 8532

1The intended use is only included for Class IIb and class III devices

Certificate number: 85320192511
Product list issue date: 11 April 2025