UK MDR – Decision Report

Certificate No:	85320192511
Task ID:	CA00303-005
Date:	26 September 2024
Handled by:	Michelle Sentker
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Graphic Controls Acquisition Corp
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Purpose

Assessment to issue a new certificate according to Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002].
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
Desktop review ACTY-2024-230020	*Remote*	*Tuomas Toivonen*	*19 August 2024*

Scope of assessment

Class I Measuring Device

Result

0 minor/major non-conformities were noted during the audit.

Certificate Valid from

26 September 2024

Conclusions/Decisions

Referring to the above a Certificate of Conformance with Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002] will be issued. The Certificate is valid for products specified in the “UK 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 UK Ltd, Academy Place, 1-9 Brook Street, Brentwood, Essex CM14 5NQ (imnb@intertek.com).

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 UK Ltd has the right to review this documentation.

Intertek Medical Notified Body UK Ltd
Approved Body UK MDR 2002

Brian Mather
Certification Authority (Audit)