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EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Certificate Number:
41377034-01

Initial Certification Date:
8 September 2010*

Certificate Valid from:
20 January 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Organization:

Graphic Controls Acquisition Corp.

Main Site: 400 Exchange St, Buffalo, New York 14204, United States

Product Category:

- Thermal recording chart paper

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

*Previously certified by Intertek AMTAC (NB0473) to date 20 June 2018

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

20 January 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

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 Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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MDD – Product List

Products included in the certificate no: 41377034-01
Issued to: **Graphic Controls Acquisition Corp.**
400 Exchange St
Buffalo, New York 14204
United States

Product category	Type/Model designation	Class	Measuring	GMDN code (not mandatory)	Date added
Thermal recording chart paper					
	CMS 4305 (40/CA) 30597226	I(m)	Yes	-	20 June 2018
	LTN 781-080-12 01082320	I(m)	Yes	-	20 June 2018
	HP M1910A (40/CA) 30748696	I(m)	Yes	-	20 June 2018
	HP 9270–0485 10643709	I(m)	Yes	-	20 June 2018
	CMS 4305 BAO 30767589	I(m)	Yes	-	20 June 2018
	GE Paper Fetal Monitors 50-210, 40/CASE (100MM) 5818864 32029833	I(m)	Yes	16754	28 May 2019
	MRC HP M1910A 32017245	I(m)	Yes	-	20 June 2018
	HP 9270–0484 10005156	I(m)	Yes	-	20 June 2018
	HP M1913A 30791761	I(m)	Yes	-	20 June 2018
	EDN F6/F9 32024161	I(m)	Yes	-	20 June 2018
	HP M1911A (40/CA) 32016831	I(m)	Yes	-	20 June 2018
	MRC HP M1911A 32018592	I(m)	Yes	-	20 June 2018
	SPA AMS-31-0427 32024151	I(m)	Yes	-	20 June 2018
	EDN CADENCE (MS1-01921) 32020618	I(m)	Yes	-	20 June 2018
	HP M1911A (ARCHIVAL/25YR) 32021183	I(m)	Yes	-	20 June 2018
	SPA AMS-31-0432 32024300	I(m)	Yes	-	20 June 2018

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MDD – Product List

Product category	Type/Model designation	Class	Measuring	GMDN code (not mandatory)	Date added
	CMS 4483 30589132	I(m)	Yes	-	20 June 2018
	CMS 4525AAO 32016790	I(m)	Yes	-	20 June 2018
	MRY PM-9000 32017121	I(m)	Yes	-	20 June 2018
	Paper VSD Fetal Monitor 30-24- 4-/CS 2104907-001	I(m)	Yes	-	13 September 2018
	Z-Fold Fetal Monitor 2104908-001	I(m)	Yes	-	13 September 2018

Date of Issue: 20 January 2020

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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MDD – Decision Report

Certificate No: 41377034-01
Date: 20 January 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Graphic Controls Acquisition Corp.
Attn: Kim Miller
400 Exchange St
Buffalo, New York 14204
United States

Purpose	Assessment to issue a new certificate due to early five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
Activity	Certification audit was performed 20 August 2019 in Buffalo, New York by Albert Cefalo and Orpha James.
Scope of assessment	Thermal recording chart paper, Class I (m)
Result	6 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	20 January 2020
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko 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 Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Bob Andersson
Certification Authority MDD