

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.

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

Certificate Number:

41377034-01

Initial Certification Date:

8 September 2010*

Certificate Valid from:

20 January 2020

Certificate Expiry Date:

26 May 2024



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

Bob Andersson

Certification Authority MDD

Intertek Semko AB, Kista, Sweden

20 January 2020

Signed Date

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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 Notified Body.

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



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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Product category	Type/Model designation	Class	Measuring	GMDN code (not mandatory)	Date added
	CMS 4483 30589132	I(m)	Yes	-	20 June 2018
	MRN 9100-025-50 32020410	I(m)	Yes		March 11, 2020
	SPC AMS-31-0432 32020898	I(m)	Yes		March 11, 2020
	VYR 2009828-AAO 6P/C 32026920	I(m)	Yes		March 11, 2020
	VYR 2009828-CAO 40P/C 32026921	I(m)	Yes		March 11, 2020
	VYR 2009828-DAO 40P/C 32026922	I(m)	Yes		March 11, 2020
	VYR 2009828-FAO 40P/C 32026923	I(m)	Yes		March 11, 2020
	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: 11 March 2020

Intertek Semko AB
Notified Body MDD


Peter Nermander
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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