DECLARATION OF CONFORMITY

Application of Council Directive(s):	Council Directive 93/42/EEC (as amended 2007/47/EC)
Conformity Assessment Route:	Annex IX, excluding Section 4, of Council Directive 93/42/EEC
Standards to which Conformity is Declared:	EN 980: 2008 EN 1041: 2008 EN 15223-1: 2012 EN ISO 11137-2: 2015 EN ISO 10993-1:2012 EN ISO 11137-1:2006 EN ISO 13485: 2003 EN ISO 14971: 2012 EN 556-1: 2001 EN ISO 10079-2: 2014 EN ISO 11137-2:2006 EN 556-1:2001
Manufacturer's Name and Address:	RMS Medical Products 24 Carpenter Road Chester, New York 10918 United States of America
Authorised European Representative:	RMS Medical Products UK, Ltd. 123a Allerton Road Mossley Hill, Liverpool L18 2DD United Kingdom
Notified Body:	British Standards Institution (BSI) Phone: +44 345 086 9001 EC Code Number: 0086
Device:	Res-Q-Vac® Hand Held Medical Suction
Type of Device:	Suction system
Device classification per MDD 93/42/EEC:	See Appendix I
GMDN Code	Airway emergency clearance/suction system, manual [47368]
Component Numbers:	See Appendix I

RMS™ MEDICAL PRODUCTS

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Appendix I

Device	Product Code	Classification	Rationale	Supporting Reference
Reusable vacuum pump handle. Pump handle Bulk Pack Military. RES-Q-VAC pump no accessories.	P0000000B P0000000BM P0000000N	Class I	The pump is non-invasive device. Per Rule 1, all non-invasive devices are in Class I	MDD 93/42/EEC 1993 Annex IX Section III Classification Rule 1
300ml graduated canister, canister cap and patient label with or without FSP (Optional Full Stop Protection Filter) and with or without endotracheal adapter. Also Pediatric non sterile canister assembly.	NS CAN FSP CAN FSP CAN ET NS CAN ET PN CAN	Class I	The canisters are non-invasive. Per Rule 1, all non-invasive devices are in Class I	MDD 93/42/EEC 1993 Annex IX Section III Classification Rule 1
Variety of non-sterile whistle tipped catheters	R001S000N R001R000N UP083514 UP103514 UP143514 UP083514E UP103514E UP143514E	Class I	All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I: 1. are in Class I if they are intended for transient use, 2. except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,	MDD 93/42/EEC 1993 Annex IX Section III Classification Rule 5

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MEDICAL PRODUCTS

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Res-Q-Vac LED Light Source	RQVLED	Class I	All other active devices are in Class I	MDD 93/42/EEC 1993 Annex IX Section III Classification Rule 12

I hereby declare that the medical device (s) specified above conforms to the above directive(s) & standard(s) and that RMS is exclusively responsible for the declaration of conformity.

Harry Shaffer, Director of Regulatory & Quality Affairs

10/20/18
Date

Rev C.

RMS™ MEDICAL PRODUCTS

DECLARATION OF CONFORMITY

Revision Number	Description of Change	Name	Date
A	Initial Release	Andrew I. Sealfon	1/18/2013
B	Changed the format of document, changed notified body from DQS to BSI, changed EU Rep address from 146 Allerton Rd, changed classification of device from Class IIa to classifying each component, updated GMDN code information, updated information of standards.	L. Joseph	10/2/2017
C	GMDN term changed from "Manual emergency suction system"	L. Joseph	2/21/2018
D	Updated Signature	C. Lacatena	10/19/2018