

Declaration of Conformity

We,



10601 Calle Lee #190
Los Alamitos, CA 90720 USA
(714) 418-1091 (714) 418-1095 Fax

declare that the products listed on this document (below):

Item: RESUSCITATOR UNIT & RELATED ACCESSORIES
Product: Resuscitator Unit, CPR Mask, Rescue Pump

BVM (Class IIa)

T30511
T30512
T30513
T30514
T30515
T30516
T30531
T30532
T30533
T30534
T30535
T30536

MVP (Manual Vac Pump / Rescue Pump)
(Class I)

T60540

MVP Accessories (Class I)

Collection Bottle w/ large bore catheter

CPR Mask (Class I)
T50520

BVM Accessories (Class IIa)

O2 Supply Line
O2 Reservoir
PVC & Silicone Masks Sizes: 0,1,2,3,4 & 5
Flapper Valves
PEEP Valves
Accumulator Adapter

Guedel Airways

Nasopharyngeal Airways

Berman Airways

to which this declaration relates is in conformity with the following standards or other normative documents:

Standard	Test Report / Certification No. if applicable	Issued By
ISO 10993-5	C-49000	ITS Cranleigh (UK) Ltd.
ISO 10993-10	C-49000	ITS Cranleigh (UK) Ltd.
EN 980:2008	~	~
PrEN 1041: 2008	~	~
EN 1441:1997	~	~
ISO 8382: 1998	~	~
ISO 5356-1:1987	~	~
ASTM F920-93	~	~
ISO 14971:2007	~	~
ISO 9001: 2008	2004-OSL-AQ-7517	Det Norske Veritas
ISO 13485:2003	2004-OSL-AQ-7517	Det Norske Veritas
CE MDD 93/42/EEC		

EUROPEAN CONTACT:
Ferno Washington Italia s.r.l.
via Benedetto Zallone n.26
40066, Pieve di Cento (Bo) - Italy

Notified Body:
DQS Medizinprodukte GmbH
TÜV Rheinland LGA Products GmbH

following the provisions of Directive 93/42/EEC as amended by 2007/42/EC, Annex I, Annex V, Annex VII

Spiracle Technology, LLC
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Michael Sarné, Managing Director

May 28, 2021

Date