

DECLARATION OF CONFORMITY**We, Clement Clarke International Limited,**

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Essex, CM20 2TT
United Kingdom
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Declare under our sole responsibility that the product listed below to which this declaration relates, is in conformity with the applicable provisions of Directive 93/42/EEC, Annex V (Metrology Aspects only).

Refer to Product Schedule on pages 2 and 3 for a complete list of part codes and descriptions.

DEVICE GROUP: EXPIRATORY PEAK FLOW METERS
DESCRIPTION: Various

CLASSIFICATION: The device has been classified as Class I, with a measuring function, in accordance with Annex IX, essential requirements of the Council Directive 93/42/EEC.

The Notified Body responsible for carrying out those elements of the Directive requiring NB intervention is SGS Belgium NV, SGS House, Noorderlaan 87, 2030 Antwerp, Belgium (CE1639)

MDD CLASSIFICATION: **Class I** (with a measuring function)
Rule 5: Invasive device with respect to a body orifice, transient use, non-active medical device

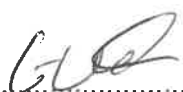
UMDNS Code & Term: 15965 - Flowmeters, Pulmonary Function

GMDN CODE & Term: 46872- Peak Flow Meter, Manual

Refer to Harmonised Standards HSCCI2015426 for a complete list of applied standards

EU Authorised Rep: HAAG-STREIT SURGICAL GmbH & Co. KG
Rosengarten 10
22880 Wedel, Germany

Authorised By:

Signed: 

Mr G Ostacchini
Group QA/RA Manager
On behalf of:

Clement Clarke International Ltd
Edinburgh Way, Harlow
Essex, CM20 2TT
United Kingdom

Date: 1st Dec 2020

Product Schedule

Description	Quantity	Part Code	GMDN	UMDNS	GTIN
Mini-Wright Peak Flow Meter (Standard Range)					
MWPFM STD ATS CLAM	1	3103085	46872	15965	0502 3323 0308 56
MINIWRIGHT PFM STD EURO	1	3103387	46872	15965	0502 3323 0002 24
MWPFM 2 STD EURO - DOH	1	3103388	46872	15965	0502 3323 0338 88
MWPFM STD EU NTH. H. SER	1	3103297	46872	15965	0502 3323 0022 42
MW STD ATS (MEDLINE)	1	3103842	46872	15965	0502 3323 0014 50
MWPFM STD ATS - MATSUYOSHI	1	3103213	46872	15965	0502 3323 0166 38
MWPFM STD ATS CLAM (TRI-ANIM)	1	3203030	46872	15965	0081 2574 0261 15
MWPFM STD ATS ATM SINGLE	1	3103104ATM	46872	15965	0502 3323 0020 99
MINI WRIGHT STD SLOVENIA & POLAND	1	3103398	46872	15965	0502 3323 0019 00
MWPFM STD EU + SECURITY LABEL	1	3103259	46872	15965	0502 3323 0155 18
Mini-Wright Peak Flow Meter AFS (Paediatric Range)					
MWPFM AFS LOW RANGE ATS	1	3104050	46872	15965	0502 3323 0405 03
MINIWRIGHT PFM AFS L/R EURO	1	3104710	46872	15965	0502 3323 0016 58
MWPFM AFS EU SCALE L/R W/M CLM	1	3104124	46872	15965	0502 3323 0009 41
MWPFM L/R W/EUROPEAN SCALE DOH	1	3104708	46872	15965	0502 3323 0016 10
MWPFM L/R ATS ATM SINGLE	1	3104001ATM	46872	15965	0502 3323 0011 39
MINIWRIGHT PFM AFS LOW RANGE BREAS	1	31047142	46872	15965	0502 3323 0259 68
Airzone Range Peak Flow Meters					
AIRZONE BLUE DOH EU SCALE	1	3130160	46872	15965	0502 3323 3016 04
AIRZONE BLUE ATS (EUROPE) CE	1	3130057	46872	15965	0502 3323 0013 13
AIRZONE BLUE ATS (CAN) SINGLE	1	3130045	46872	15965	0502 3323 0012 14
AIRZONE BLUE ATS ATM SINGLE	1	3130045ATM	46872	15965	0502 3323 0010 23
AIRZONE ATS (AUSTRALIA)	1	3130145	46872	15965	0502 3323 3014 51
AIRZONE EVALUPEAK ATS CURAPLEX	1	3130180	46872	15965	0081 2574 0254 15
AIRZONE (MEDLINE) 12X36 BOX	1	3130185	46872	15965	0502 3323 0012 52
AIRZONE MATSUYOSHI	1	3130035	46872	15965	0502 3323 3003 55
AIRZONE EXPORT EU	1	31301612	46872	15965	0502 3323 0258 83
OMRON PFM20	1	3130170	46872	15965	0502 3323 3017 03
Accessories					
Windmill Assy (AFS) Box 50	1	3104272	N/A	N/A	0502 3323 0004 60
Windmill Assy (Airzone) Box 50	1	3104262	N/A	N/A	0502 3323 0004 84