

DECLARATION OF CONFORMITY

We, Clement Clarke International Limited,
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Declare under our sole responsibility that the product(s) listed below to which this declaration relates, is in conformity with the applicable provisions of Directive 93/42/EEC, Annex V.

Refer to page 2 and 3 of this document for a complete list of part codes and descriptions.

DESCRIPTION: Various

CLASSIFICATION: The device(s) have been classified as class IIa, 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 IIa**

Rule 2 – Non-invasive device intended for channelling liquids or gases for the purpose of eventual infusion, administration or introduction into the body.

Rule 5 – Invasive device with respect to a body orifice, Intended for short term use while connected to an active medical device.

UMDNS Code & Term 12449 Masks, Air-Oxygen, Aerosol Administration

GMDN NUMBER & TERM: 62042 – Nebulising system delivery set, reusable

Refer to Harmonised Standards HSCCI2015615 for a complete list of applied standards

EU Authorised Rep: Sensus Consulting Ltd
The Black Church, St Marys Place
Dublin, D07 P4AX

Authorised By:

Signed: 
Mrs K Mouncey
QA/RA Team Leader
On behalf of;
Clement Clarke International Ltd
Edinburgh Way, Harlow
Essex, CM20 2TT,
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Date: 18th Dec 2020

Description	Part Code	GMDN	UMDNS	GTIN Number
Kits without masks or mouthpieces (Rule 2)				
Micro-Neb Nebuliser (50)	L6006	62042	12449	0502 3323 0515 47
Micro-Neb Nebuliser (50s) Bel (Belgium)	L6006/BEL	62042	12449	0502 3323 0005 83
Micro-Neb & Angle connector	L6007	62042	12449	0502 3323 0019 62
Micro-Neb & Angle connector (France)	L6007/F	62042	12449	0502 3323 0260 88
Micro-Neb & Angle connector (Italy)	L6007/I	62042	12449	0502 3323 0023 03
Nebuliser Neb Cup (Box 25)	L3605489	62042	12449	0502 3323 0506 94
Kits with masks (Rule 2)				
Aerosol Mask Adult	L3000	62042	12449	0502 3323 0007 74
Aerosol Mask Paediatric	L3002	62042	12449	0502 3323 0007 81
Micro-Neb Adult Mask Kit	L6003	62042	12449	0502 3323 0513 63
Micro-Neb Adult Mask Kit FR (Mediflux)	L6003/F	62042	12449	0340 1043 6663 71
Micro-Neb Adult Mask Kit IT (Italy)	L6003/I	62042	12449	0502 3323 0239 64
Micro-Neb Adult Mask Kit /BEL (Belgium)	L6003/BEL	62042	12449	0502 3323 0006 20
Micro-Neb Paediatric Mask Kit	L6004	62042	12449	0502 3323 0514 31
Micro-Neb Paed Mask Kit French (Mediflux)	L6004/F	62042	12449	0340 1043 6662 03
Micro-Neb Paed Mask Kit / B (Belgium)	L6004/BEL	62042	12449	0502 3323 0006 13
Micro-Neb Paed Mask Kit IT (Italy)	L6004/I	62042	12449	0502 3323 0022 11
Adult Neb Kit Wymedical	L6012	62042	12449	0502 3323 0018 18
Paed Neb Kit Wymedical	L6013	62042	12449	0502 3323 0018 01
Year Pack Adult Mask	L6120	62042	12449	0502 3323 0240 22
Actineb Adult Year Pack	L3103001	62042	12449	0502 3323 0236 74
Actineb Child Year Pack	L3702080	62042	12449	0502 3323 0237 04
Microneb Paed Year Pack (1)	3300191	62042	12449	0502 3323 0130 95
Microneb Adult Year Pack	3300192	62042	12449	0502 3323 0014 43
Neb Set Adult (Box 25)	L3605491	62042	12449	0502 3323 0507 17
Neb Set Child (Box 25)	L3605492	62042	12449	0502 3323 0507 31

Adult Face Masks (Box 25)	L3605518	62042	12449	0502 3323 0507 55
Child Face Masks (Box 25)	L3605519	62042	12449	0502 3323 0507 62
Kits with mouthpieces (Rule 5)				
Micro-Neb Mouthpiece Kit	L6005	62042	12449	0502 3323 0514 93
Micro-Neb Mouthpiece Kit /Bel (Belgium)	L6005/BEL	62042	12449	0502 3323 0006 06
Micro-Neb Mouthpiece Kit FR (Mediflux)	L6005/F	62042	12449	0340 1043 6664 32
Micro-Neb Mouthpiece	L6008	62042	12449	0502 3323 0019 93
Micro-Neb Inline Adaptor Kit	L6009	62042	12449	0502 3323 0239 88
Inline Adaptor & Mouthpiece	L6010	62042	12449	0502 3323 0239 95
Micro-Neb Mouthpiece Kit	L6011	62042	12449	0502 3323 0240 08
Year Pack Mouthpiece	L6122	62042	12449	0502 3323 0240 39
Adult Year Pack	L3605122	62042	12449	0502 3323 0506 18
Child Year Pack	L3605123	62042	12449	0502 3323 0236 98
Child Year Pack (12)	L3605124	62042	12449	0502 3323 0237 11
Adult Year Pack (12)	L3605125	62042	12449	0502 3323 0237 28
Mouthpiece (Box 25)	L3605490	62042	12449	0502 3323 0005 14
Neb Set Mouthpiece (Box 25)	L3605493	62042	12449	0502 3323 0237 66
1000 Adult Year Pack	3605542	62042	12449	0502 3323 0016 72
1000 Paed Year Pack	3605543	62042	12449	0502 3323 0022 80
Travel-Air Paed Year Pack	3605544	62042	12449	0502 3323 0022 97
Travel-Air Adult Year Pack	3605545	62042	12449	0502 3323 0016 89
Airmed 1000 Paediatric Consumables (25)	36055472	62042	12449	0502 3323 0266 44