



EC Declaration of Conformity

Legal Manufacturer: Williams Medical Supplies Ltd, The Maerdy Industrial Estate North, Rhymney, Tredegar, Gwent, NP22 5PY, UK
Tel: 00 + 44 (0) 1685 846666
Email: qualityassurance@wms.co.uk

Contract Manufacturer: Polymed (Xiamen) Plastic Industrial Company, Ltd, Unit B, block No. G, Warehouse & Process Complex, Building Xiangyu F.T.Z., Xiamen, China

EU Representative: DCC Vital, Fannin House, South County Business Park, Leopardstown, Dublin 18, Ireland

Notified Body: GMED SAS (0459), 1 Rue Gaston Boissier, 75015, Paris, France
Tel: +33 (0) 1 40 43 37 00

Brand/Type: Merlin Medical Resuscitation

Product: See Appendix

Classification Rule: IIa - as per Rule 2. All non-invasive devices intended for Channelling or storing Blood, Body Liquids, Cells, Body Liquids, Cells or Tissues, Liquids or Gases for the purpose of eventual infusion, administration or introduction into the body, if they may be connected to a class IIa, IIb or III active device.

Country of Origin: China

Technical File: TCF 008b

GMDN: See appendix

Declaration:

Williams Medical Supplies Ltd are hereby responsible for this declaration which states that the device specified above conforms to the General Safety and Performance Requirements (Annex I) of the Medical Device Regulation 2017/745 of April 5, 2017.

The stated products are designed and manufactured by Williams Medical Supplies Ltd, in accordance with the scope of a quality system which meets the requirements of ISO 13485:2016 and the Medical Device Regulation 2017/745 of April 5, 2017.


Notified Body GMED have approved the Williams Medical Ltd quality assurance system and issued ISO 13485:2016 certificate number: 35881 Rev 0 issued on 31st October 2019 & expires 20th November 2021.

The representations above are accurate as of the date of this document.

Amendment History		
Version	Date	Amendment
1		Created
2	29 th December 2017	Reviewed & amended - various items now discontinued & removed from range
3	30 th July 2018	Reviewed as a result of the SGS audit findings – change to the annex used to provide classification of the products
4	17 th June 2019	Transferred to a new generic template, listing all Resuscitation Devices in 1 document & a review of standards listed
5	25 th June 2020	Fully reviewed following Notified body audit Jan 2020, new template used & GMDN codes added.

Issued By: Helen Davies

Date: 25th June 2020

Signature: 

Title: Head Of Regulatory Affairs

Place of Issue: Williams Medical Supplies Ltd, The Maerdy Industrial Estate North, Rhymney, Tredegar, Gwent, NP22 5PY, UK.

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Appendix

Product Code	Description	UDI	GMDN
D44574	Peep Valve & Adaptor Set - Disposable	5060265380052	46823
W4441/2	First Response Reservoir Bag [Adult & Child] - Disposable	5060265380342	34877
W4443/1	1 Piece Air Cushioned Mask [Child]- Disposable	5060265380762	17170
W4446/1	1 Piece Air Cushioned Mask [Infant]- Disposable	5060265380366	17170
W4446/2	First Response Reservoir Bag [Infant] - Disposable	5060265380373	34877
W4452/4	2 Piece Mask Size 4 [Adult]- Autoclavable	5060265380380	17170
W4452/5	2 Piece Mask Size 5 [Adult]- Autoclavable	5060265380397	17170
W44525	Resuscitation Set with Pop Off [Adult] - Autoclavable	5060265380403	36690
W4453	Merlin E Resuscitation Mask – [Latex Free] - Disposable	5060265380410	17170
W4453/1	Valve for Merlin E Resuscitation Mask – [Latex Free] - Disposable	5060265380427	58941
W4454	Resuscitation Set with Pop Off [Child] - Autoclavable	5060265380434	36690
W4454/2	Donut Mask Size 2 [Child]- Autoclavable	5060265380441	17170
W4454/3	2 Piece Mask Size 3 [Child]- Autoclavable	5060265380458	17170
W4455	Merlin E shield Mouth to Mask Face Shield - Disposable	5060265380465	63222
W4456	Resuscitation Set with Pop Off [Infant] - Autoclavable	5060265380472	36690
W4456/0	Donut Mask Size 0 [Infant]- Autoclavable	5060265380489	17170
W4456/1	Donut Mask Size 1 [Infant]- Autoclavable	5060265380502	17170
W44574	Patient Valve with Pop Off - Autoclavable	5060265380496	14337
W4460	Air Intake Valve - Autoclavable	5060265380519	46823
W4472	Resuscitation Set with Pop Off [Adult] - Disposable	5060265380533	35693
W4473	Resuscitation Set without Pop Off [Adult] - Disposable	5060265380137	35693
W4475	Resuscitation Set with Pop Off [Child] - Disposable	5060265380540	35693
W4477	Resuscitation Set with Pop Off [Infant] - Disposable	5060265380557	35693
W4545	Merlin E shield Mouth to Mask Face Shield in a Keyring Pouch - Disposable	5060265380571	63222