

Declaration of Conformity

In accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.


Manufacturer:	Timesco Healthcare Limited
Address:	3 Carnival Park, Basildon, SS14 3WN, United Kingdom
Manufacturer SRN:	GB-MF-000021764
EU Authorised Representative:	Advena Limited Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013, Malta
EU Authorised Representative SRN:	MT-AR-000000234
Notified Body & Identification No.:	Not Applicable
Conformity Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 and Annex IV after drafting up the technical documentation as laid out in Annexes II and III of the Regulations (EU) 2017/745.
EC Certificate:	Not Applicable

Device Details

Product Name:	Single Use Blade Video Laryngoscope
Product Classification:	Class I , in accordance with Rule 5 of Regulations (EU) 2017/745, Annex VIII
Basic UDI-DI:	50553828MDTF012K6
Intended Purpose:	The Timesco video laryngoscope is intended for use by qualified professionals to obtain a clear, unobstructed view of the airway and vocal cords for medical procedures.

We, Timesco Healthcare Ltd, as the sole manufacturer declare that the products listed in Appendix I meet the Council provisions that apply to them. The products are in conformity with the common specification (where applicable) as listed in Appendix II.

This declaration hereby authorises the CE mark to be affixed to the products listed below, after drawing up the technical documentation in accordance to Annexes II, III & IV of the Regulation (EU) 2017/745.

Review & Approval:	Stuart Norris 	Date:	09 Jan 2023
Function:	Quality & Regulatory Manager (Person Responsible for Regulatory Compliance)	Place:	Timesco Healthcare Limited 3 Carnival Park, Basildon, SS14 3WN, United Kingdom
Declaration of Conformity Reference:	MDTF012-EUDOC	Revision:	02

Appendix I - Product Listing / Schedule

The products in the scope of this declaration of conformity are tabulated below, categorised by the relevant European Medical Device Nomenclature (EMDN).

EMDN	Product Code	Product Description
Z12021004	4000.310.50	Optima View video Laryngoscope Handle and LCD Display 3.75" for Single-Use Blades

Accessories		
EMDN	Product Code	Product Description
Z12021099	4000.900.10	Optima View HDMI Cable
	4000.900.11	Optima View USB Cable
	4000.900.12	Optima View 5V/2A Adapter

Appendix II - Applicable Standards

The products listed in Appendix I are in conformity with the Standards and Common Specifications (CS) as outlined below.

Standard / CS / Document	Description
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 13485:2016	Medical Devices - Quality management systems – Requirements for regulatory purposes
EN ISO 15223-1:2021	Medical Devices - Symbols to be used with information to be supplied by the manufacturer
EN ISO 10993-1:2020	Biological evaluation of medical devices
EN ISO 20417:2021	Information to be supplied by the manufacturer
EN ISO 17664:2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
IEC / EN 60601-1	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
IEC / EN 60601-1-2	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility

Revision History

Revision	Approval	Date	Description of Changes
01	Stuart Norris	27 Oct 2022	First Revision.
02	Stuart Norris	09 Jan 2023	Addition of applied standards.