

**DECLARATION OF CONFORMITY**

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, and
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, as amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015 (RoHS3).

Document Number 80016303

Version P

Product Name

Fiber Optic Laryngoscope

Manufacturer's Name and Business Address

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153
USA

SRN: US-MF-000013394

Declaration of Conformity Validity

ISO 13485 #314505 MP2016 Expiry Date: 2024-11-07

EC REP

Welch Allyn Limited,
Navan Business Park, Dublin Road,
Navan, Co. Meath, C15 AW22
Ireland

SRN: IE-AR-000000768

Object of the declaration



Laryngoscopes

Intended Purpose

A rigid laryngoscope is intended to be used to examine and visualize a patient's upper airway and aid in the placement of a tracheal tube.

Medical Device Conformity Assessment Route Annex

Annex II and Annex III

Medical Device Classification

Class I

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Medical Device Classification Rule	Rules 5, 13																														
Standards	Refer to Appendix A																														
<div style="display: flex; gap: 10px;"> <div style="border: 1px solid black; padding: 2px 5px;">REF</div> <div style="border: 1px solid black; padding: 2px 5px;">#</div> </div>	<p style="text-align: center;">901038: Laryngoscope 901087: Instrument Handle</p> <p style="text-align: center;">Laryngoscope</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">65122</td> <td style="text-align: center;">68696</td> </tr> <tr> <td style="text-align: center;">68696-LED</td> <td style="text-align: center;">69696</td> </tr> <tr> <td style="text-align: center;">69696-LED</td> <td style="text-align: center;">69697</td> </tr> <tr> <td style="text-align: center;">69697-LED</td> <td></td> </tr> </table> <p style="text-align: center;">Miller Fiber Optic Blades</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">68060</td> <td style="text-align: center;">68061</td> </tr> <tr> <td style="text-align: center;">68062</td> <td style="text-align: center;">68063</td> </tr> <tr> <td style="text-align: center;">68064</td> <td style="text-align: center;">68065</td> </tr> </table> <p style="text-align: center;">MacIntosh Fiber Optic Blades</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">69061</td> <td style="text-align: center;">69062</td> </tr> <tr> <td style="text-align: center;">69063</td> <td style="text-align: center;">69064</td> </tr> </table> <p style="text-align: center;">English MacIntosh Fiber Optic Blades</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">69211</td> <td style="text-align: center;">69212</td> </tr> <tr> <td style="text-align: center;">69213</td> <td style="text-align: center;">69214</td> </tr> </table> <p style="text-align: center;">Instrument Handle</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;">60813</td> <td style="text-align: center;">60813-LED</td> </tr> <tr> <td style="text-align: center;">60814</td> <td style="text-align: center;">60814-LED</td> </tr> <tr> <td style="text-align: center;">60815</td> <td style="text-align: center;">60815-LED</td> </tr> <tr> <td style="text-align: center;">60713</td> <td style="text-align: center;">60835</td> </tr> </table>	65122	68696	68696-LED	69696	69696-LED	69697	69697-LED		68060	68061	68062	68063	68064	68065	69061	69062	69063	69064	69211	69212	69213	69214	60813	60813-LED	60814	60814-LED	60815	60815-LED	60713	60835
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60814	60814-LED																														
60815	60815-LED																														
60713	60835																														
GMDN Code and Term	15076 Rigid intubation laryngoscope, reusable																														
UMDNS Code and Term	15076 Laryngoscopes, Rigid																														
Basic UDI-DI	0732094GMN901038F7 0732094GMN901087FL																														



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Approval

DocuSigned by Jeffrey E. Thompson

17-Jan-2023 | 14:11:11 CST



Jeffrey E. Thompson

I approve this document
17-Jan-2023 | 14:10:53 CST

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Jeffrey E Thompson, Manager, Regulatory Affairs	Date	Skaneateles Falls NY, USA Place of Issue
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Appendix A: Standards and Common Specifications

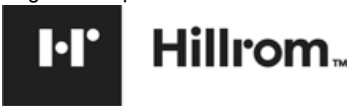
Standards Applied	Number	Version/Date of Issue	Title
Regulation 2017/745	EN 60601-1	2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN ISO 7376	2009	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation
	EN ISO 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	EN ISO 10993-1	2018	Biological evaluation of medical devices – Part 1: Evaluation and Testing.
	EN ISO 10993-5	2009	Biological evaluation of medical devices — Part 5: Tests for in-vitro cytotoxicity
	EN ISO 10993-10	2013	Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity
	EN ISO 14971	2019	Medical devices-Application of risk management to medical devices
	EN 60601-1-2	2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
	EN 60601-1-6	2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance.
	EN 62366-1	2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
EN ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General Requirements	
	EN ISO 20417	2021	Medical devices – Information to be supplied by the manufacturer
Directive 2011/65/EU + (EU) 2015/863	EN IEC 63000	2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances



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Document Change History

Version	Description	Author	Date
A	Updated from DOC-MDD-064 Rev. 2 to add Fiber Optic Laryngoscope kits and update to SAP format, including new DQS name.	Susan Schmidt	2010-08-16
B	Updated classification Rules from 1 & 12 to rule 5. Clarified REF (model) numbers of blades, handles & kits. Clarified ISO standard to ISO 7376-3. Deleted revision dates to all applied standards. Removed non safety stds. Removed EN 60601-1-2. Updated to FCD-0011, Rev 5	Jamie Strong	2011-02-01
C	Revised for certificate references	P Oris	2011-09-18
D	Converted to latest FMT DIR 80019151 Ver. B. Added RoHS statement and EN 50581 standard.	Jamie Strong	2014-07-15
E	Updated DoC to include REF "901038, LARYNGOSCOPE" and "901087, INSTRUMENT HANDLE"	M. McGovern	2015-10-09
F	Updated # to add new LED Handle Model Numbers; Updated <i>Standards Applied</i> to add EN/ISO 7376 for the new Model numbers & corresponding Blades & added ISO 10993-1 (this is a correction.)	M. Pellenz	2016-02-17

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G	Updated to new format. Updated GMDN code 15076 from 15076 – “Laryngoscope, intubation” to 15076 – “Rigid intubation laryngoscope, reusable” to match GMDN database. Removed the following kit numbers as they are OB: 65101, 65102, 65103, 65104, 65121, 65123, 65124, 65125, 65126 Added standards: EN 60601-1-2, EN 60601-1-6 and EN 62366	B. Rice	2019-02-27
H	Updated for EUMDR	C. Lefancheck	05/27/2021
J	Updated for EUMDR change	C. Lefancheck	06/16/2021
K	Updated for RoHS 3	K Ockenfels	07/22/2021
L	Updated for RoHS, Added SRN, Reviewed	K Ockenfels	08/18/ 2021
M	Updated to new template, added Intended Purpose statement, updated standards list.	K Ockenfels, K Love	11/09/2021
N	Updated standards list to include EN ISO 14971:2019 and EN ISO 20417:2021.	K Ockenfels	04/11/2022
P	Updated DOC ISO 13485 Expiration date	M Solanki	12/06/2022