EU Declaration of Conformity (DoC)

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EU DoC ID	**80016303 Rev R**

Manufacturer Name and Address:

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

USA

Manufacturer Single Registration Number (SRN): US-MF-000013394

Authorised Representative Name and Address:

Authorised Representative Name and Address:

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

Ireland

Authorised Representative Single Registration Number (SRN): IE-AR-000000768

+++ We as Manufacturer declare, under our sole responsibility, that the product(s) listed below conform to the applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and the following Directive(s), Regulation(s) and Common Specification(s). +++

Other relevant Directives, Regulations and Union Legislations that the device is in conformity with:

- 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).

Common Specifications Applied: NA

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Product/Trade Name and Product Code or REF. number:

REF	#	Description
Laryngoscope FO		
65122	901038	UNIV F/O LARYN SET/C/STB HNDL
68696	901038	F/O LARYNGOSCOPE SET-MILLER
68696-LED	901038	F/O LARYNGOSOCPE SET-MILLER W/LED
69696	901038	F/O LARYNGOSCOPE SET-MAC
69696-LED	901038	F/O LARYNGOSCOPE SET-MAC W/LED
69697	901038	F/O LARYNGOSCOPE SET-E MAC
69697-LED	901038	F/O LARYNGOSCOPE SET-E MAC W/LED
Miller Fiber Optic Blades		
68060	901038	#0 MIL F/O LARYNGOSCOPE
68061	901038	#1 MIL F/O LARYNGOSCOPE
68062	901038	#2 MIL F/O LARYNGOSCOPE
68063	901038	#3 MIL F/O LARYNGOSCOPE
68064	901038	#4 MIL F/O LARYNGOSCOPE
68065	901038	#00 MIL F/O LARYNGOSCOPE
MacIntosh Fiber Optic Blades		
69061	901038	#1 MAC F/O LARYNGOSCOPE
69062	901038	#2 MAC F/O LARYNGOSCOPE
69063	901038	#3 MAC F/O LARYNGOSCOPE
69064	901038	#4 MAC F/O LARYNGOSCOPE
English MacIntosh Fiber Optic Blades		
69211	901038	#1 E-MAC F/O LARYNGOSCOPE ASSY
69212	901038	#2 E-MAC F/O LARYNGOSCOPE ASSY
69213	901038	#3 E-MAC F/O LARYNGOSCOPE ASSY
69214	901038	#4 E-MAC F/O LARYNGOSCOPE ASSY

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REF	#	Description
Instrument Handle		
60813	901087	LIGHTWEIGHT F/O LARYNGOSCOPE
60813-LED	901087	LIGHTWEIGHT F/O LARYNGOSCOPE W/LED
60814	901087	LIGHTWEIGHT F/O LARYNGOSCOPE
60814-LED	901087	LIGHTWEIGHT F/O LARYNGOSCOPE W/LED
60815	901087	STUBBY F/O LARYNGOSCOPE HANDLE
60815-LED	901087	STUBBY F/O LARYNGOSCOPE HANDLE W/LED
60713	901087	LIGHTWEIGHT RCHGBL F/O LARYNGOSCOPE
60835	901087	3.5V RECHG F/O LARYNGO HANDLE

Intended Purpose/Use: 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.

Device Risk Class: Class I

Medical Device Classification Rule: Rules 5, 13

Product Basic UDI-DI Number:

Laryngoscope: 0732094GMN901038F7

Instrument Handle: 0732094GMN901087FL

MDR EU Certificate(s) No.: N/A Class 1 Device

Conformity Assessment Description/Annexes: Annex II and Annex III

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Notified Body Name and Address: N/A, It's a Class 1 device Notified Body Identification Number: NA

+++ This Declaration is made on the following basis:
• For devices with a MDR EU Certificate issued by a Notified Body:
  ○ The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate.
  ○ The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate.
• For Class I devices (*that are non-sterile, have no measurement function or are not reusable surgical instruments*) the DoC declares conformity to the product lots released after the date of signature.
• Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).
• Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++

Authorised Signatory:	
Name and Title:	Joseph Olsavsky, Sr. Director Regulatory Affairs
Function:	PRRC
Place of Issue:	Skaneateles Falls, NY, USA.
Date of Issue:	13 November 2024
Signature:	JOSEPH OLSAVSKY *Electronically signed by: JOSEPH OLSAVSKY* *Reason: I approve this document* *Date: Nov 15, 2024 09:14 EST*

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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 *Standards Applied* 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
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

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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
R	Transformed to Baxter template	Farees Sultana	13 November 2024