**DECLARATION OF CONFORMITY**

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

| Manufacturer’s Name and Business Address: | Welch Allyn, Inc.  
4341 State Street Road  
Skaneateles Falls, NY 13153, USA |
|------------------------------------------|--------------------------------------------------|
| **EC REP** | Regulatory Affairs Representative  
Welch Allyn Limited  
Navan Business Park  
Dublin Road  
Navan, County Meath  
Republic of Ireland |
| **Product Name** | Fiber Optic Laryngoscopes |
| **REF** | 901038, LARYNGOSCOPE  
901087, INSTRUMENT HANDLE |
| **#** | Blades:  
68060, 68061, 68062, 68063, 68064, 68065 (Miller Fiber-Optic Blades)  
69061, 69062, 69063, 69064 (MacIntosh Fiber-Optic Blades)  
69211, 69212, 69213, 69214 (English MacIntosh Fiber-Optic Blades)  
Handles:  
60813, 60813-LED, 60814, 60814-LED, 60815, 60815-LED, 60713, 60835 (Fiber Optic Battery Handles)  
Kits:  
65122, 68696, 68696-LED, 69696, 69696-LED 69697 & 69697-LED |
| **Radio equipment** | Not Applicable, no radio |
| **Object of the declaration** | Not Applicable, no radio |
| **Accessories and components** | Not Applicable, no radio |
| **Medical Device Conformity Assessment Route Annex** | VII |

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1 applicable to the medical devices directive, 93/42/EEC  
2 applicable to the radio equipment directive, 2014/53/EU  
3 applicable to the RoHS directive, 2011/65/EU

Template DIR 80019151 Ver. F
Medical Device Classification¹:
1
Medical Device Classification Rules¹:
5
GMDN Code and Term¹:
15076 - Rigid intubation laryngoscope, reusable
UMDNS Code and Term¹:
15076 - Laryngoscopes designed with a non-flexible (i.e., rigid) structure that can only follow a straight path through the airway. They are constructed of metal and contain straight or curved blades for manipulation of the tongue and pharynx during the procedures. Rigid endoscopes are frequently used for insertion of endotracheal tubes.

Standards Applied (Standards are applicable to the medical device directive, unless otherwise indicated):

<table>
<thead>
<tr>
<th>Number</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 50581³</td>
<td>Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances</td>
</tr>
<tr>
<td>EN / IEC 60601-1</td>
<td>Medical Electrical Equipment, Part 1: General Requirements for Safety</td>
</tr>
<tr>
<td>EN/IEC 60601-1-6</td>
<td>Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability</td>
</tr>
<tr>
<td>EN/IEC 62366</td>
<td>Medical Devices - Application of Usability Engineering To Medical Devices</td>
</tr>
<tr>
<td>ISO 7376-3</td>
<td>Laryngoscope fittings - Part 3: Fibre-illuminated re-usable rigid laryngoscopes</td>
</tr>
</tbody>
</table>
| EN / ISO 7376   | Anaesthetic and respiratory equipment -- Laryngoscopes for tracheal intubation
               | NOTE: Compliance report applicable to blades used with -LED handles. |
| EN / ISO 10993-1 | Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process |

Authorised Signatory:

Fiona Butler, Manager Regulatory Affairs

2019-05-15
Navan
Place of Issue

¹ applicable to the medical devices directive, 93/42/EEC
² applicable to the radio equipment directive, 2014/53/EU
³ applicable to the RoHS directive, 2011/65/EU