DECLARATION OF CONFORMITY
(in accordance with ISO/IEC 17050-1)

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 | 4341 State Street Road
| Skaneateles Falls, NY 13153, USA | Skaneateles Falls, NY 13153, USA

| Regulatory Affairs Representative | Welch Allyn Limited
| Navan Business Park | Navan Business Park
| Dublin Road | Dublin Road
| Navan, County Meath | Navan, County Meath
| Republic of Ireland | Republic of Ireland

| Product Name¹,²,³ | Retinoscope
| 901024, RETINOSCOPE |

| Radio equipment²: | Not Applicable
| Object of the declaration²: | Not Applicable
| Accessories and components²: | Not Applicable

| Medical Device Conformity Assessment Route Annex¹: | VII

| Medical Device Classification¹: | 1
| Medical Device Classification Rules¹: | 12

| GMDN Code and Term¹: | 32712 - Retinoscope, battery-powered

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

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UMDNS Code and Term: 17840 - Retinoscope

<table>
<thead>
<tr>
<th>Standards Applied</th>
<th>Number</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Standards are applicable to the medical device directive, unless otherwise indicated):</td>
<td>EN 50581</td>
<td>Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances</td>
</tr>
<tr>
<td></td>
<td>EN 60601-1</td>
<td>Medical Electrical equipment – Part 1: General requirements for Safety</td>
</tr>
<tr>
<td></td>
<td>EN 60601-1-2</td>
<td>Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard Safety requirements for medical electrical systems</td>
</tr>
</tbody>
</table>

Authorised Signatory:

Fiona Butler, Manager Regulatory Affairs
{EU Authorised Representative}

2019-07-25
Navan

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

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