

# EU Declaration of Conformity (DoC)

**NOTICE:** Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

<b>EU DoC ID</b>	80027998 Revision N										
<p>Manufacturer Name and Address:                  Welch Allyn, Inc.                  4341 State Street Road                  Skaneateles Falls, NY 13153 USA                  Manufacturer Single Registration Number (SRN): US-MF-000013394</p>											
<p>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</p>											
<p>+++ 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). +++</p>											
<p>Other relevant Directives, Regulations and Union Legislations that the device is in conformity with:</p> <ul style="list-style-type: none"> <li>• 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 (CCV).</li> </ul>											
<p>Common Specifications Applied: Not Applicable</p>											
<p>Product/Trade Name and Product Code or REF. number:                  901087: Instrument Handle</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">719-3</td> <td>LI-ION PLUS USB HANDLE FOR DESK CHARGER</td> </tr> </table> <p>901001: Accessory, Eye, Ear, Nose &amp; Throat</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">719-DSK</td> <td>Welch Allyn Universal Desk Charger</td> </tr> <tr> <td>719-DSK-2</td> <td>Welch Allyn Universal Desk Charger EU</td> </tr> <tr> <td>719-DSK-3</td> <td>Welch Allyn Universal Desk Charger ISR</td> </tr> <tr> <td>719-DSK-4</td> <td>welch Allyn Universal Desk Charger UK</td> </tr> </table>		719-3	LI-ION PLUS USB HANDLE FOR DESK CHARGER	719-DSK	Welch Allyn Universal Desk Charger	719-DSK-2	Welch Allyn Universal Desk Charger EU	719-DSK-3	Welch Allyn Universal Desk Charger ISR	719-DSK-4	welch Allyn Universal Desk Charger UK
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Intended Purpose/Use: 901087: Instrument Handle The 719-3 Li-Ion Plus USB Handle (719-3 USB Handle) is intended for use as a power source for all Welch Allyn standard 3.5 V instrument heads.  901001: Accessory, Eye, Ear, Nose & Throat The chargers are intended to charge Welch Allyn rechargeable 2.5 V and 3.5 V handles.
Device Risk Class: Class I, Rule 13
Product Basic UDI-DI Number: 901087: Instrument Handle: 0732094GMN901087FL 901001: Accessory, Eye, Ear, Nose & Throat: 0732094GMN901001EG
MDR EU Certificate(s) No.: Not Applicable
Conformity Assessment Description/Annexes: Annex II and III
Notified Body Name and Address: Not Applicable Notified Body Identification Number: Not Applicable
+++ This Declaration is made on the following basis: <ul style="list-style-type: none"><li>• For devices with a MDR EU Certificate issued by a Notified Body:<ul style="list-style-type: none"><li>○ The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate.</li><li>○ The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate.</li></ul></li><li>• For Class I devices (<i>that are non-sterile, have no measurement function or are not reusable surgical instruments</i>) the DoC declares conformity to the product lots released after the date of signature.</li><li>• Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).</li><li>• 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. +++</li></ul>

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Authorized Signatory:	
Name and Title:	Joseph Olsavsky, Sr. Director Regulatory Affairs
Function:	PRRC
Place of Issue:	Skaneateles Falls, NY, USA
Date of Issue:	13 Nov 2024
Signature:	<b>Signature:</b> JOSEPH OLSAVSKY <small>Electronically signed by: JOSEPH OLSAVSKY Reason: I approve this document Date: Nov 15, 2024 08:54 EST</small>

**Email:** joseph\_olsavsky@baxter.com