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 80027998 Version L

Product Name	Power Handles & Chargers
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: 2022-12-08
EC REP	Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland SRN: IE-AR-000000768
Object of Declaration	 Enhance Li-ion Handle
Intended Purpose	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.
Medical Device Conformity Assessment Route Annex	Annex II and Annex III
Medical Device Classification	Class I
Medical Device Classification Rule	Rule 13
Standards	Refer to Appendix A
REF #	901087: Instrument Handle 719-3
GMDN Code and Term	34158 Secondary battery

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UMDNS Code and Term	18557 Power Supplies
Basic UDI-DI	0732094GMN901087FL

Accessories

Object of Declaration	 Universal Desk Charger
Intended Purpose	The chargers are intended to charge Welch Allyn rechargeable 2.5 V and 3.5 V handles.
Medical Device Conformity Assessment Route Annex	Annex II and Annex III
Medical Device Classification	Class I
Medical Device Classification Rule	Rule 13
Standards	Refer to Appendix A

REF #

901001 ACCESSORY, EYE, EAR, NOSE & THROAT

719-DSK
719-DSK-2
719-DSK-3
719-DSK-4

GMDN Code and Term	17115 Non-invasive device battery charger
UMDNS Code and Term	18557 Power Supplies
Basic UDI-DI	0732094GMN901001EG

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Approval

Joshua Kim, Sr Manager, Global Regulatory Assurance	2022 · 04 · 19	Skaneateles Falls, NY USA
	Date	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 10993-1	2018	Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process
	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 13485	2016	Medical Devices – Quality Management Systems - Requirements for Regulatory Purposes
	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 - Collateral Standard: Usability
	EN 62366-1	2015	Medical Devices - Part 1: Application of Usability Engineering to Medical Devices
	EN 62304	2015	Medical device software - Software life-cycle processes
	EN 62281	2012	Safety of primary and secondary lithium cells and batteries during transport
	EN 62474	2018	Material declaration for products of and for the electrotechnical industry
	EN 62133-2	2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

	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 14971	2019	Medical devices - Application of risk management to medical devices
	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

Document Change History

Version	Description	Author	Date
A	Initial Release	C. Lefancheck	03/22/2021
B	Updates to GMDN Codes	C. Lefancheck	03/24/2021
C	Updates to UMDNS Codes	C. Lefancheck	04/12/2021
D	Updated for EUMDR	C. Lefancheck	05/25/2021
E	Rev'd again for EUMDR update	C. Lefancheck	05/27/2021
F	Resigned for translations	C. Lefancheck	06/16/2021
G	Update for RoHS3	K Ockenfels	07/22/2021
H	Updated for RoHS3, added SRN, added rev history.	K Ockenfels	08/17/2021
J	Removed EN 1041	F.Ding	08/23/2021
K	Updated to new template, added Intended Purpose statement, removed desk charger part numbers that where specific to Aus, NZ and China, they have their own DoCs, updated standards list	K Ockenfels	11/11/2021
L	Update for EN ISO 20471:2021 and EN ISO 14971:2019	S. Co	04/11/2022