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 80016309	Version P	
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 the declaration	  	
Intended Purpose	The handles are intended to power various accessory heads including otoscopes, ophthalmoscopes, retinoscopes, strabismoscopes, episcopes, illuminators and transilluminators.	
Medical Device Conformity Assessment Route Annex	Annex II and Annex III	
Medical Device Classification	Class I	
Medical Device Classification Rule	Rules 1, 13	
Standards	Refer to Appendix A	

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REF #

901087: INSTRUMENT HANDLE

71000	71001- B	71001-C	71010
71020	71021-C	71062	71064
71066	71670	71902	71904
71906	71907	71910	71911
72800	72801	72830	71000- A
71000-B	71000-C	71020-A	71020-B
71020-C	71930		

GMDN Code and Term	34158 Secondary battery
UMDNS Code and Term	18557 Power Supplies
Basic UDI-DI	0732094GMN901087FL

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Accessories

Object of the declaration	
Intended Purpose	719 USB Charger, Universal Desk Charger 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 901087: INSTRUMENT HANDLE
GMDN Code and Term	17115 Non-invasive Device Battery Charger
UMDNS Code and Term	18557 Power Supplies
Basic UDI-DI	0732094GMN901001EG 0732094GMN901122EV

71142	71943
71942	71960-POD

71712	71714	71716
71732	71734	71736
71062-C	71064-C	71140
71144	71146	71955

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Approval

Joshua Kim, Sr. Manager Global Regulatory Affairs	2021-12-22	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 13485	2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
	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 skin sensitization
	EN 60601-1-2	2015	Medical electrical equipment_- Part_1-2: General requirements for basic safety and essential performance_- Collateral standard: Electromagnetic compatibility_- Requirements and tests
	EN 60601-1-6	2015	Medical electrical equipment_- General requirements for basic safety and essential performance_- Collateral Standard: Usability
	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 62281	2012	Safety of primary and secondary lithium cells and batteries during transport
	EN 62366-1	2015	Medical devices_- Application of usability engineering to medical devices
	EN 62304	2015	Medical device software - Software life-cycle processes
	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

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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
Version	Description	Author	Date
A	Initial Release		
B	Updated to Form Revision 5 and corrected Certificate References	P. Oris	2011-10-10
C	Added # 71032 and 71020-A, 71064-C missing from the original	P. Oris	2012-07-11
D	Added # 70500F, 70720F, 71001-B, 71001-C, 71010F, 71021-C, 71021-VCA, and 71670F. Updated to latest Form version. Added Annex for Saudi Arabia Submission. Added # 71942. Updated to new Format.	M. McGovern	2014-05-06
E	Converted to latest FMT DIR 80019151 Ver. B. Added RoHS statement and EN 50581 standard. Removed handle numbers 60200, 60300, 60305, 60400, 60710, which appear on 80016304 and 60813, 60814, 60815, which appear on 80016303	Jamie Strong	2014-07-15
F	Removed 60762, 60764, 71021-VCA, 71616, 72820, 72831 (OB); 71010F, 71116, 71118, 71119, 71500, 71670F (not extended to Plant 1062); 71114 (no Sales); 71032, 71036 (901000 ACCESSORY / COMPONENT) Updated DoC to include REF 901087, INSTRUMENT HANDLE and 901001, ACCESSORY, EYE, EAR, NOSE & THROAT	M. McGovern	2017-07-27
G	Added 719 USB Charger – 71955 and REF 901122, ACCESSORY ELECTRICAL Updated format to meet new Directive requirements	B. Killoran	2018-04-24
H	Deleted 70000, 70500, 70500F, 70700, 70710, 70715, 70720, 70720F, 70762, 70764 (OB), 71900 (DC)	M. McGovern	2019-09-27
J	Updated for EUMDR	C Lefancheck	2020-03-12
K	Rev'd for EUMDR	C. Lefancheck	2020-09-17
L	Rev'd for EUMDR	C Lefancheck	2021-06-15
M	Updated for RoHS3	K Ockenfels	2021-07-21
N	Updated for RoHS3, added SRN Number.	K Ockenfels	2021-08-17

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P	Updated to New Template, added Intended Purpose Statement and updated standards list.	K Ockenfels	2021-11-09