

PROCEDURE APPROVALS

Note: Date of last approval will serve as the Approval Date for this document.

Name	Function	Signature	Date
Kathy Reddig	Regulatory	krreddig	12/10/2020

Declaration of Conformity (V2a-12291-2797)

Manufacturer: CONMED Corporation
525 French Road
Utica, New York 13502-5994 USA

EC Representative: MDSS GmbH
Schiffgraben 41
D-30174 Hannover, Germany

Notified Body: British Standards Institute (BSI)
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands

Notified Body ID No.: 2797

Classification/Rule: IIa, Rule 6

Conformity Assessment/ MDD 93/42/EEC, Annex II excluding section 4

Certificate: CE587783

GMDN Code/Term: 12291 – Laparoscope, Rigid, Optical
10198 - Arthroscope

Product Family: Endoscope Systems

Catalog No.	Description	Technical File Number	Date 1 st CE Marked
HD1000	10mm, 0 Degree HD Autoclavable Eyecup Scope	10-01	Jun, 2009
HD1030	10mm, 30 Degree HD Autoclavable Eyecup Scope	10-01	Jun, 2009
HD1044	10mm, 45 Degree HD Autoclavable Eyecup Scope	10-01	Jun, 2009
HD5500	5.5mm, 0 Degree HD Autoclavable Eyecup Scope	10-01	Jun, 2009
HD5500XL	5.5mm, 0 Degree HD Extended Length Autoclavable Eyecup Laparoscope	10-01	Dec, 2009
HD5530	5.5mm, 30 Degree HD Autoclavable Eyecup Scope	10-01	Jun, 2009
HD5530XL	5.5mm, 30 Degree HD Extended Length Autoclavable Eyecup Laparoscope	10-01	Dec, 2009
HD5544	5.5mm, 45 Degree HD Autoclavable Eyecup Scope	10-01	Jun, 2009
8191-11	3DHD Dual Channel Stereo Endoscope Autoclavable 10mm 0 Degree	13-02	Oct, 2012
8191-12	3DHD Dual Channel Stereo Endoscope Autoclavable 10mm 30	13-02	Oct, 2012

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Catalog No.	Description	Technical File Number	Date 1st CE Marked
	Degree		
8191-13	3DHD Dual Channel Standard Length Stereo Endoscope Autoclavable 10mm, 0 Degree	17-01	Jun, 2017
8191-14	3DHD Dual Channel Standard Length Stereo Endoscope Autoclavable 10mm, 30 Degree	17-01	Jun, 2017
UHD1000	10mm, 0 Degree UHD Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD1030	10mm, 30 Degree UHD Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD1044	10mm, 45 Degree UHD Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD1000XL	10mm, 0 Degree UHD Extended Length Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD1030XL	10mm, 30 Degree UHD Extended Length Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD1044XL	10mm, 45 Degree UHD Extended Length Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD5500	5.5mm, 0 Degree UHD Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD5530	5.5mm, 30 Degree UHD Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD5544	5.5mm, 45 Degree UHD Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD5500XL	5.5mm, 0 Degree UHD Extended Length Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD5530XL	5.5mm, 30 Degree UHD Extended Length Autoclavable Eyecup Laparoscope	15-01	Nov-2015
UHD5544XL	5.5mm, 45 Degree UHD Extended Length Autoclavable Eyecup Laparoscope	15-01	Nov-2015

Runout existing supply (no new manufacturing)

Catalog No.	Description	Technical File Number	Date 1st CE Marked
HD5545XL	5.5mm, 45 Degree HD Extended Length Autoclavable Cartridge Laparoscope	10-01	Dec, 2009
HD1001	10mm, 0 Degree HD Autoclavable Cartridge Scope	10-01	Jun, 2009
HD1031	10mm, 30 Degree HD Autoclavable Cartridge Scope	10-01	Jun, 2009
HD1045	10mm, 45 Degree HD Autoclavable Cartridge Scope	10-01	Jun, 2009
HD5501	5.5mm, 0 Degree HD Autoclavable Cartridge Scope	10-01	Jun, 2009
HD5531	5.5mm, 30 Degree HD Autoclavable Cartridge Scope	10-01	Jun, 2009
HD5545	5.5mm, 45 Degree HD Autoclavable Cartridge Scope	10-01	Jun, 2009
T1000B	10mm, 0 Degree Extended Length Autoclavable Eyecup Laparoscope	10-02	Nov, 2003
T1030B	10mm, 30 Degree Extended Length Autoclavable Eyecup Laparoscope	10-02	Nov, 2003
T1044B	10mm, 45 Degree Extended Length Autoclavable Eyecup Laparoscope	10-02	Nov, 2003

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We, the manufacturer, hereby declare that the medical devices listed above conform to the applicable provisions of Directive 93/42/EEC, concerning medical devices.

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DOC Change History**

Date	Rev.	Description of Change	Reason for Change
09-Oct-2014	01	Moved catalog numbers from DOC# 2A-12291 Rev.08 to DOC# 2A-12291-C.	Changed labeled manufacturer from ConMed Linvatec to ConMed Corporation.
31-January-2018	02	Moved catalog no. HD1001; HD1031; HD1045; HD5501; HD5531; HD5544XL; HD5545; T1000B; T1030B; T1044B to run-out table Removed Cat# HD5501XL; HD5531XL from DOC-2a-12291-C Rev. 01 Fixed spelling of laparoscope	Items moved from active to runout status. Item obsolete Typo error
09 Dec 2020	03	Updated the NB# from 0086 to 2797 Added UHDXXX and 8191-XXX to this DoC because of the Brexit change.	Per Brexit Change