CONMED

Doc Number: **REG1580568** Revision Number: **E**

Title: **DoC for TD-AV-ESI-001**

Effective Date: Feb 10, 2021

PROCEDURE APPROVALS

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

Name	Function	Signature	Date
Kathy Reddig	Regulatory	kreddig	02/10/2021

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Declaration of Conformity

Manufacturer: **CONMED Corporation** Address: 525 French Road

Utica, New York 13502 USA

MDSS GmbH European Auth. Rep.:

Schiffgraben 41 D-30175 Hannover

Germany

Notified Body BSI Group The Netherlands B.V.

Address: Say Building, John M. Keynesplein 9, 1066EP

> Amsterdam Netherlands

NB Identification #: N/A

Annex II and III, of the Regulation (EU) 2017/745 on Medical **Conformity Assessment:**

Devices

Self-Certified **EC Certificate Number:**

Device / Risk Classification: Class I Rule per Annex VIII: Rule 10

Product Family: AEI- Active Endoscopic Instruments

Intended Purpose: Endoscopic instruments that are intended to be used in surgical procedures including, Orthopedic, laparoscopic, urologic sinuscopic, plastic and other microscopic

surgeries.

Devices:

Reference Number	Product Description	Date 1st CE Marked	Basic UDI-DI	Technical Document #
AV4132	Looking Glass TM 4K Integrated Visualization System	Jul 2020	084585405069CK	AV-AEI-001
AV41CHE	Looking Glass Camera Head – 4K 3MOS Eye-cup	Jul 2020	084585405076CG	
AV41CON	Looking Glass Cable Connector Interface	Jul 2020	084585405070C4	
AV41LG	Electronic Light Guide	Jul 2020	084585405071C6	
AVELG51	ELG Dyonics / Wolf Adapter	Jul 2020	084585405089CR	
AVELG52	ELG ACMI Adapter	Jul 2020	084585405090CA	
AVELG53	ELG Conmed threaded adapter	Jul 2020	084585405091CC	
AVELG53SA	Scope to threaded adapter	Jul 2020	084585405095CL	
AV41TLS8	Looking Glass Translator LS8000	December 2020	0653405986719R	

This declaration is issued under the sole responsibility of the manufacturer.

DT00000443 Rev. C Page 1 of 3

CONMED

Title: DoC for TD-AV-ESI-001 Revision Number: E Effective Date: Feb 10, 2021 Doc Number: REG1580568

> We, the manufacturer, hereby declare that the medical devices listed on this declaration conform with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices.

Place of issue of the DoC: **ConMed Corporation**

525 French Road Utica, NY- 13502

USA

Date of issue of the DoC: See Windchill approver Coversheet **CONMED**

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Revision History

Revision #	Reason for Change
1	Transferred the DoC content to the MDR Template from MDD (REG1521509)
2	Added AV41TLS8 to the DoC
3	Revised DoC due to the revision of technical document
4	Revised DoC to add intended purpose
5	Revised Product Family from ESI to AEI