CONMED Title: 2A-38559-2797 Tubing sets with filter

Doc Number: **REG1609670** Revision Number: **A** Effective Date: **Dec 29, 2020** 

## **PROCEDURE APPROVALS**

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

Name	Function	Signature	Date	
Kathy Reddig	Regulatory	kreddig	12/29/2020	

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Declaration of Conformity 2A-38559-2797

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 Standard Institute (BSI)

Say Building,

John M. Keynesplein 9, 1066 EP Amsterdam

Netherlands

**Notified Body ID No.:** 2797

Classification/Rule: Class IIa, Rule 2

**Conformity Assessment/** 

Full Quality Assurance per Council Directive 93/42/EEC,

Certificate:

Annex II, excluding Section 4/ No. CE 587783

GMDN Code/Term:

38559 / Insufflation gas conditioning tubing set

**Product Family:** Powered Surgical Instruments

Catalog No.	Description	Technical File Number	Date 1 <sup>st</sup> CE Marked
C7010	Laparoflator Tubing, with filter and male luer connectors	10-01	June 1998
GS1016	Insufflation Tubing Set, with filter	10-01	May 2003

## **Runout existing supply (no new manufacturing)**

Catalog No.	Description	Technical File Number	Date 1st CE Marked
N/A			

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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## Declaration of Conformity 2A-38559-2797 DOC Change History

Date	Rev.	Description of Change	Reason for Change
28 Dec 2020	A	Moved product from 2A- 38559-C	Notified Body change from BSI UK to BSI
			Netherlands

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