

	AQ-0002	Rev. 00	DATA REVISIONE:	01/04/2020
	Preparazione:	QA	Approvazione:	GM

EU Declaration of Conformity

Manufacturer: 3A HEALTH CARE S.r.l.
Address: Via Marziale Cerutti, 90F/G
25017 Lonato del Garda (BS)
Italy
SRN: IT-MF-000009298
Product Category: N/A
Product Description: Disposable Suction Liner 1 Lt
Model (code): 3AC461
Basic UDI-DI: 803371701ASP44942AN
UDI-DI/EAN: 8033717011573
Intended purpose: The device is intended for the collection of different types of fluids during surgeries.

Classification for MDR: Class I (MDR Annex VIII Rule 1)
Product Category for RoHS: Category 8 (Medical devices)

We, 3A HEALTH CARE S.r.l., herewith declare, under our sole responsibility, that the above mentioned product meets the provisions of the following European Union Regulations, Council Directives and Standards. All supporting documentation is retained at the premises of the manufacturer. This declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

General applicable regulations: Medical Devices Regulation 2017/745

Standards: EN ISO 10079-1:2015
EN 1041:2008+A1:2013
EN ISO 15223-1:2021
IEC 62366-1:2015
EN ISO 13485:2016/A11:2021
EN ISO 14971:2019/A11:2021

Notified Body: N.A
Address: N.A
ID No: N.A
Certification Registration No: N.A

General applicable directives: RoHS Directive 2011/65/EU, Delegated Directive (EU) 2015/863

Standards EN IEC 63000:2018

Place / Date Lonato del Garda, 2024/10/21
Signature:

Name: Simone Abate
Position: Quality Assurance & Regulatory Affairs Director

 **3A HEALTH CARE S.r.l.**
Via Marziale Cerutti, 90F/G
25017 Lonato del Garda (BS) - Italy
Tel. +39 030 9133177 - Fax +39 030 9919114
Codice Fiscale e Partita IVA 03262640984

