

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

EC Declaration of Conformity

Manufacturer (SRN): 3A HEALTH CARE S.r.l. (SRN *****)
Address: Via Marziale Cerutti, 90F/G
25017 Lonato del Garda (BS)
Italy

Product Category: Not applicable
GMDN: Suction system canister liner (44942)
Product Description: Disposable Suction Liner 1 Lt
Model (code): 3AC461
UDI-DI: 803 371 701 157 3
Classification for MDR: Class I (MDR Annex VIII Rule 1)
Product Category for RoHS: Category 8 (Medical devices)

3A HEALTH CARE S.r.l. declares that above mentioned product meets the provisions of the following European Committee Regulations, Council Directives and Standards under the sole responsibility. All supporting documentations are 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 15223-1:2016 IEC 62366-1:2015 EN ISO 13485:2016 EN ISO 14971:2019
Notified Body:	N.A
Address:	N.A
ID No:	N.A
Certification Registration No:	N.A
General applicable directives:	RoHS Directive 2011/65/EU
Standards	EN 50581:2012

Place / Date Lonato del Garda, 2021/05/06
Signature:
Name: Simone Abate
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