GaleMed (Xiamen) Co., Ltd.
Xiamen Area of China (Fujian) Pilot Free Trade Zone,
39, Section 3, Haijing East Road 361026 Fujian Province, China
Telephone: +86 0592 688 0588

Declaration of Conformity

We, GaleMed (Xiamen) Co., Ltd., hereby confirm that the products listed in Table 1, which are delivered or will be delivered by GaleMed, are substantially equivalent to the products of GaleMed. They are identical from the technological characteristics.

Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety effectiveness, biocompatibility, standards and other characteristics, as applicable.

We also declare that the products listed in Table 1 comply with the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices, as amended by 2007/47/EC and is verified in accordance with Annex II, excluding section 4.

Certificate No.: 9989-2017-CE-RGC-NA-PS Rev.2.0
Notified Body: DNV
Notified Body No.: 2460
Authorized Representative: Obelis S.A.
Address: Bd. Général Wahis 53, 1030 Brussels, Belgium

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Management Representative: Jeann Wang

Signature: Jeann Wang

Date: 2022-01-24

DMP:2022-01-25-435245 V1.0

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Table 1

Teleflex P/N	GaleMed ERP P/N	GaleMed SAP P/N	Description	Classification
41042P	3644-TF	XTF0007	OM-2 Oxygen Mask Child	Class IIa
1041P	3645-TF	XTF0008	OM-2 Oxygen Mask Adult	Class IIa
41098P	3754-TF	XTF0010	Oxygen Mask, Venturi	Class IIa
1083P	3733-TF	XTF0009	AM-2 Aerosol Mask, Adult	Class IIa
41892P	3558-TF	XTF0003	NebEasy Nebulizer	Class IIa
41893P	3569-TF	XTF0004	Neb-Easy Aerosol Mask Adult	Class IIa
41894P	3570-TF	XTF0005	Neb-Easy Aerosol Mask Child	Class IIa
1090P	36053-TF	XTF0006	MASK,MEDIUM CONC,TBG STD ,ADULT	Class IIa

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