June 13th , 2024

C/0449/24/GF/mab

To: **FAZZINI S.R.L.**
STRADA STATALE PADANA SUPERIORE, 317
20055 - VIMODRONE (MI)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking Certificate **N° G2 044963 0035 Rev. 01 - Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement n. 8580940, in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

FAZZINI S.R.L.
STRADA STATALE PADANA SUPERIORE, 317
20055 - VIMODRONE (MI)
ITALY

Table n.1

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**Device name under MDD corresponding to the device under MDR application**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application**
NEBULIZZATORI A PISTONE – POWERED PISTON NEBULISERS Models: 1. F-205 2. F-210 PRO	IIa	Aspiratori, Nebulizzatori a diaframma, a pistone e ad ultrasuoni, Palloni per la respirazione e maschere per anestesia, Palloni e maschere per rianimazione, Cannule nasali, tubi di connessione per ossigeno e aerosol terapia // Suction pumps, Powered nebulisers, diaphragm, piston and ultrasonic, Rebreathing bags and anesthesia	Certificate N° G2 044963 0035 Rev. 01 issued by NB n° 0123 on 2021/03/29.

		masks, Reanimation bags and face masks, cannula and connecting tubes for oxygen and aerosol therapy	
ASPIRATORI MEDICALI (MODELS reported into QI) already marked CE: ASPIRATORI – SUCTION PUMPS Trade models: (marked CE): F-100 F-100/4 F-100/F F-100/F4 F-100/F4D F-100/FD F-100D F-100D/4 F-100DR F-100DR/4 F-100DR/F F-100DR/F4 F-100R F-100R TH F-100R/4 F-100R/F F-100R/F4 F-170/B F-170/B.OB F-170/B2 F-170/B2.OB F-18 BATTERY F-18 BATTERY TH F-18.00 F-18.OB F-18.OB BATTERY F-18.TH F-18/2.00 F-18/2.OB F-18/2.TH F-18B/2.00 F-18B/2.OB F-18B/2.TH F-20.00 F-20/2.00 F-30.00 F-30.00.OB F-30.00/P F-30.00/PF F-30.05 F-30.05/M F-30.05/P F-30.05/PF	IIa	Aspiratori, Nebulizzatori a diaframma, a pistone e ad ultrasuoni, Palloni per la respirazione e maschere per anestesia, Palloni e maschere per rianimazione, Cannule nasali, tubi di connessione per ossigeno e aerosol terapia // Suction pumps, Powered nebulisers, diaphragm, piston and ultrasonic, Rebreathing bags and anesthesia masks, Reanimation bags and face masks, cannula and connecting tubes for oxygen and aerosol therapy	Certificate N° G2 044963 0035 Rev. 01 issued by NB n° 0123 on 2021/03/29.

F-30.05/PFUNI			
F-30.05/PM			
F-30.20			
F-30.20.OB			
F-30.20/P			
F-30.20/PF			
F-30.25			
F-30.25/M			
F-30.25/PF			
F-30.40			
F-30.40.OB			
F-30.40/P			
F-30.40/PF.OB			
F-30.45			
F-30.45/P			
F-30.60			
F-30.60.OB			
F-30.60/P			
F-30.60/PF			
F-30.65			
F-30.65/P			
F-30.65/PF			
F-30.65/PFUNI			
F-31.00			
F-31.00 TH			
F-31.00/P			
F-31.00/P TH			
F-31.00/PF			
F-31.00UNI			
F-31.OB			
F-35.00.OB			
F-35.00/PF.OB			
F-35.40.OB			
F-35.45/P.OB			
F-35.60.OB			
F-35.60/PF.OB			
F-35.65.OB/PF			
F-36.OB			
F-40.OB			
F-40/2.OB			
UN-F-100/F			
UN-F-30.65/P			
UN-F-30.65/PF			
F-31.05			
F-31.05/P			
F-31.20			
F-31.20/P			
F-31.25			
F-31.25/P			
F-31.40			
F-31.45			
F-31.60			
F-31.60/P			
F-31.65			
F-31.65/PF			
F-35.00			
F-35.00/P			
F-35.00/PF			
F-35.05			

F-35.05/PF			
F-35.20			
F-35.25			
F-35.40			
F-35.45/PF			
F-35.60			
F-35.60/P			
F-35.65			
F-35.65/P			
F-35.85/P			
F-35.86/P			
F-35.95			
F-35.95/P			
F-36.00			
F-36.10			
F-36/2.00			
F-36/2.10			
F-40.00			
F-40.10			
F-40/2.00			
F-40/2.10			
F-60			
F-60 TH			
F-60/4			
F-60/4D			
F-60/F			
F-60/F4			
F-60/F4D			
F-60/FD			
F-60B			
F-60B TH			
F-60B/4			
F-60B/F			
F-60B/F4			
F-60B/R			
F-60B/R4			
F-60B/RF4			
F-60D			
F-60R			
F-60R TH			
F-60R/4			
F-60R/F			
F-60R/F4			
F-90			
F-90/4			
F-90/F			
F-90/F4			
F-90D			
F-90D/4			
F-90D/F			
F-90D/F4			
F-90DR			
F-90DR/4			
F-90DR/F			
F-90DR/F4			
F-90R			
F-90R/4			
F-90R/F			
F-90R/F4			

F-31.65 TH F-31.65/P SA-18 SA-18B SA-30 SA-31 SA-35 SA-36 SA-60 SA-60B SA-90 SA-100			

In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

a. The above-mentioned agreement n° 8580940 was signed within 2024/09/26.
b. Bureau Veritas Italia Spa is not responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificate: N° G2 044963 0035 Rev. 01 is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2024/06/13	0	Initial issue

Gloria Focetola

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Soggetta all'attività di direzione e coordinamento da parte di Bureau Veritas SA con sede in Neuilly-sur-Seine - Francia