Air Liquide HEALTHCARE

DT/032-840 Version 03

EU DECLARATION OF CONFORMITY

We, the manufacturer, **Air Liquide Santé France**
6, rue Cognacq-Jay
75007 Paris – FRANCE

SRN: FR-MF-000001204

declare under our sole responsibility that the medical device :

Product Name	**Medical carbon dioxide for laparoscopy and colonoscopy**	
Product References	M5110S01R0A001 M5110S02R0A001 M5110S02I0A001 M5110S05R0A001 M5110S06L0A001 M5110S07R0A001 M5110S08R0A001 M5110S10I0A001 M5110S10R0A001 M5110S13R0A001	M5110S13I0A001 M5110M14R0A001 M5110M20R0A001 M5110L40R0A001 M5110L47R0A001 M5110L50R0A001 M5110L50I0A001 M5110V12Z0A001 M5110V12R0A001
Basic UDI-DI	37014892MEDICALCO2NT	
Nomenclature code according to EMDN (based on the Italian classification CND)	V0901, Clinical/therapeutic applications carbon dioxide	
Risk class of the device in accordance with the rules set out in Annex VIII of Regulation (EU) 2017/754	"Medical carbon dioxide for laparoscopy and colonoscopy" belongs to Class IIa in accordance with Rule 5 and Rule 7	

is in conformity with the Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Notified body : GMED SAS (**0459**)
1, Rue Gaston Boissier
75015 Paris - FRANCE

Conformity assessment procedure performed: ANNEX IX of the Regulation (EU) 2017/745 – Chapter I and Chapter III (Quality Management System) with assessment of Technical Documentation.

Bagneux, April 5th 2024

Jean-Christophe POIRIER
Head Pharmacist of ALSF

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Jean-Christophe Poirier
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