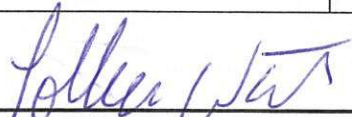


Legal Manufacturer	Vyairé Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
Product	Sterile Suction Catheters
Product Codes	See Attachment
GMDN Codes	See attachment
EC Representative	Emergo Europe - Prinsessegracht 20, 2514 AP The Hague, The Netherlands
We, the manufacturer hereby declare under sole responsibility that the products listed in this document are in conformity with the Essential Requirements of Annex I and meets the provisions of Council Directive 93/42/EEC, as amended by 2007/47/EC for medical devices. The medical devices are manufactured under control of ISO 13485:2016 Quality Management System.	
General applicable directives:	Medical Device Directive: Council Directive 93/42/EEC of 14 June, 1993 as amended, concerning medical devices
Notified Body	BSI Group The Netherlands B.V. - Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands
EC Certificate(s)	CE 703694
Annex	II, excluding Section 4
Quality System Certificate	FM 549042 MDSAP 681543
Full Quality System	ISO 13485:2016
Other applicable directive	N/A

  
 Regulatory Affairs VP/Director or Designee  
 Colleen Watson

6 DEC 2019  
 Date and Place  
 26125 N. Riverwoods Blvd.  
 Mettawa, IL 60045 USA

  
 QA Manufacturing Site Representative  
 Indra Montoya

5 Dec 19  
 Date and Place  
 Cerrada Vía de la Producción No. 85  
 PIMSA III, Mexicali, B.C. México

  
 OEM Quality Designee  
 Ilkka Lehmusvirta

05-DEC-2019  
 Date and Place  
 Kuortaneenkatu 2,  
 FI-00510, Helsinki, Finland

Attachment

Product Device Listing

Product Number	Description	EU Class	Rule(s)	GMDN Code	Type of CE Marking	Technical File
CSC110	Airlife™ Closed Suction Catheter 10 Fr	Ila	5	31249	CE 2797	RT-04
CSC110T	Airlife™ Closed Suction Catheter - Tracheostomy Length 10 Fr	Ila	5	31249	CE 2797	RT-04
CSC112	Airlife™ Closed Suction Catheter 12 Fr	Ila	5	31249	CE 2797	RT-04
CSC112T	Airlife™ Closed Suction Catheter - Tracheostomy Length 12 Fr	Ila	5	31249	CE 2797	RT-04
CSC114	Airlife™ Closed Suction Catheter 14 Fr	Ila	5	31249	CE 2797	RT-04
CSC114D	Airlife™ Closed Suction Catheter - Directional Tip 14 Fr	Ila	5	31249	CE 2797	RT-04
CSC114T	Airlife™ Closed Suction Catheter - Tracheostomy Length 14 Fr	Ila	5	31249	CE 2797	RT-04
CSC116	Airlife™ Closed Suction Catheter 16 Fr	Ila	5	31249	CE 2797	RT-04
CSC116T	Airlife™ Closed Suction Catheter - Tracheostomy Length 16 Fr	Ila	5	31249	CE 2797	RT-04
CSC205	Airlife™ Closed Suction Catheter - Neonatal, 5 FR, for use with Neo-VERSO™ Airway Access Adapter	Ila	5	31249	CE 2797	RT-04
CSC205S	Airlife™ Fluid/Access Catheter 5 FR, for use with Neo-VERSO™ Airway Access Adapter	Ila	5	31249	CE 2797	RT-04
CSC206	Airlife™ Closed Suction Catheter - Neonatal, 6 FR, for use with Neo-VERSO™ Airway Access Adapter	Ila	5	31249	CE 2797	RT-04
CSC207	Airlife™ Closed Suction Catheter - Neonatal, 7 FR, for use with Neo-VERSO™ Airway Access Adapter	Ila	5	31249	CE 2797	RT-04

CSC208	Airlife™ Closed Suction Catheter - Neonatal, 8 FR, for use with Neo-VERSO™ Airway Access Adapter	Ila	5	31249	CE 2797	RT-04
CSC100	Airlife™ Verso™ Airway Access Adapter	Ila	2	31249	CE 2797	RT-04
CSC300	Neo-Verso 'Y' Neonatal Y Airway Access Adapter	Ila	2	31249	CE 2797	RT-04
CSC400	Airlife™ Verso™ 90 Airway Access Adapter	Ila	2	31249	CE 2797	RT-04
CSC500	Airlife™ Verso™ T Airway Access Adapter	Ila	2	31249	CE 2797	RT-04
CSC600	Adapter Airway Closed Suction	Ila	2	31249	CE 2797	RT-04
K60CE	Airlife™ Tri-Flo Suction Catheter with Control, 14 Fr	Ila	2	31249	CE 2797	RT-04
K60NE	Airlife™ Tri-Flo Suction Catheter with Multifit Rigid Connector, 14 Fr	Ila	2	31249	CE 2797	RT-04
K61CE	Airlife™ Tri-Flo Suction Catheter, 10 Fr	Ila	2	31249	CE 2797	RT-04
K61NE	Airlife™ Tri-Flo Suction Catheter with Multifit Rigid Connector, 10 Fr	Ila	2	31249	CE 2797	RT-04
K62CE	Airlife™ Tri-Flo Suction Catheter, 18 Fr	Ila	2	31249	CE 2797	RT-04

GMDN Code	GMDN Term
31249	Tracheobronchial suction/insufflation catheter, dual-lumen or Tracheobronchial suction/insufflation catheter, single lumen