

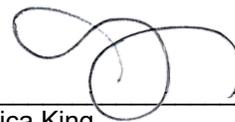
EC Declaration of Conformity

Name of Products:	BALLARD* Closed Suction Catheters
Product Codes:	See Attachment A
UMDNS Code:	16779 (Tubing, suction)
GMDN Code:	34923 (Suction System Catheter, general-purpose)
Legal Manufacturer (Place of Issue):	Avanos Medical, Inc. 5405 Windward Parkway Alpharetta, Georgia (GA) 30004, USA
EC Authorized Representative:	Avanos Medical Belgium BVBA Leonardo Da Vincilaan 1 1930 Zaventem Belgium
Product Standards:	BS EN ISO 8836:2014 ASTMF1980-07 BS EN ISO 5367:2000 (section 4.7.4) BS EN ISO 5367:2000 (section 4.6.3) BS EN ISO 5356-1:2004, (section 5.1)
Start of CE:	See Attachment A
Conformity Assessment Route:	Annex II
Device Classification, Rules:	Class IIa, Rule 2 and 5 of Annex IX
CE certificate number:	CE 711145
Notified Body:	BSI Netherlands (2797)
EC Quality System Certificate:	FM 702907

I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

All supporting documentation that contains proof of compliance to the aforementioned Directive(s) is retained under the premises of Avanos Medical, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:



Name: Monica King
Title: Associate Director, Regulatory Affairs
Avanos Medical, Inc.
Date: 6 November 2020

Attachment A (Product List)

This attachment specifies the products included in the above referenced Declaration of Conformity.

Product Code	Product Description	Start of CE mark
1910-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
1912-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
195-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
196-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
197-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
198-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
200-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
202-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
205-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
206-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
207-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
208-5	BALLARD* Closed Suction System for Neonates / Pediatrics	07/10/2019
210125-5	BALLARD* Closed Suction System for Adults	07/10/2019
210-5	BALLARD* Closed Suction System for Neonates/Pediatrics	07/10/2019
215120-5	BALLARD* Closed Suction System for Adults	07/10/2019
2151235-5	BALLARD* Closed Suction System for Adults	07/10/2019
215125-5	BALLARD* Closed Suction System for Adults	07/10/2019
2155-5	BALLARD* Closed Suction System for Adults	07/10/2019
21603-5	BALLARD* Closed Suction System for Adults	07/10/2019
216036-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
2160-5	BALLARD* Closed Suction System for Adults	07/10/2019
21606-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
21609-5	BALLARD* Closed Suction System for Adults	07/10/2019
216-5	BALLARD* Closed Suction System for Adults	07/10/2019
2201235-5	BALLARD* Closed Suction System for Adults	07/10/2019
22012356-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
220123568-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
220125-5	BALLARD* Closed Suction System for Adults	07/10/2019
220135-5	BALLARD* Closed Suction System for Adults	07/10/2019
2205-5	BALLARD* Closed Suction System for Adults	07/10/2019
22056-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
220568-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
220569-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
22059-5	BALLARD* Closed Suction System for Adults	07/10/2019
22103-5	BALLARD* Closed Suction System for Adults	07/10/2019
221036-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
221037	BALLARD* Closed Suction System for Adults	07/10/2019
221038-5	BALLARD* Closed Suction System for Adults	07/10/2019
2210386-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
2210-5	BALLARD* Closed Suction System for Adults	07/10/2019
22106-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
221069-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
22107-5	BALLARD* Closed Suction System for Adults	07/10/2019
22108-5	BALLARD* Closed Suction System for Adults	07/10/2019
221086-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
22109-5	BALLARD* Closed Suction System for Adults	07/10/2019

22113-5	BALLARD* Closed Suction System for Adults	07/10/2019
221-5	BALLARD* Closed Suction System for Adults	07/10/2019
2216-5	BALLARD* Closed Suction System for Adults	07/10/2019
2221-5	BALLARD* Closed Suction System for Adults	07/10/2019
22515-5	BALLARD* Closed Suction System for Adults	07/10/2019
2255-5	BALLARD* Closed Suction System for Adults	07/10/2019
2260-5	BALLARD* Closed Suction System for Adults	07/10/2019
22606-5	BALLARD* Closed Suction System for Adults, Wet Pak	07/10/2019
226-5	BALLARD* Closed Suction System for Adults	07/10/2019
22701356-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
2270156-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
22703-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
227036-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
227101-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
2271018-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
2271053-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
227105-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
22712183-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
22712183	BALLARD* Turbo-Cleaning Closed Suction Catheter, Double Swivel Elbow - Adult	07/10/2019
2271218-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
227121863-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
22712186-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
227135-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
22714183-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
2271418-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
227141863-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
22714186-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
2271516-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
22715-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
227156-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
2271603-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
22716036-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
2271613-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
227161-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
2271616-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
22716183-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
2271618-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
227161863-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
22716186-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
22716-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
2271653-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
227166-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
227-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults	07/10/2019
2276-5	BALLARD* Turbo-Cleaning Closed Suction System for Adults, Wet Pak	07/10/2019
25-2210-5	BALLARD* Closed Suction System for Adults	07/10/2019
24010-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, 10F	07/10/2019
240121-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, 12F	07/10/2019
24014-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, 14F	07/10/2019
240123-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, 12F	07/10/2019
240143-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, 14F	07/10/2019

240108-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, MDI,10F	07/10/2019
240128-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, MDI,12F	07/10/2019
240148-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, MDI,14F	07/10/2019
240168-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, MDI,16F	07/10/2019
24001238-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, MDI,12F	07/10/2019
2401438-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, MDI,14F	07/10/2019
2401638-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, MDI,16F	07/10/2019
240125-5	BALLARD* Multi-Access Port Replacement Catheter for Adults, Endotracheal, 12F	07/10/2019
240145-5	BALLARD* Multi-Access Port Replacement Catheter for Adults, Endotracheal, 14F	07/10/2019
240165-5	BALLARD* Multi-Access Port Replacement Catheter for Adults, Endotracheal, 16F	07/10/2019
2401253-5	BALLARD* Multi-Access Port Replacement Catheter for Adults, Tracheostomy, 12F	07/10/2019
2401453-5	BALLARD* Multi-Access Port Replacement Catheter for Adults, Tracheostomy, 14F	07/10/2019
24014598-5	BALLARD* Multi-Access Port Replacement Catheter for Adults, Endotracheal, DT,14F	07/10/2019
24014386-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, MDI,14F, WetPak*	07/10/2019
24016386-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, MDI,16F, WetPak*	07/10/2019
2401236-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, 12F, WetPak*	07/10/2019
2401436-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, 14F, WetPak*	07/10/2019
2401636-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Tracheostomy, 16F, WetPak*	07/10/2019
2401086-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, MDI,10F, WetPak*	07/10/2019
2401286-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, MDI,12F, WetPak*	07/10/2019
2401486-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, MDI,14F, WetPak*	07/10/2019
2401686-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, MDI,16F, WetPak*	07/10/2019
240126-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, 12F, WetPak*	07/10/2019
240146-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, 14F, WetPak*	07/10/2019
240166-5	BALLARD* Multi-Access Port Closed Suction System for Adults, Endotracheal, 16F, WetPak*	07/10/2019
24013-5	BALLARD* Seal Cassette	07/10/2019
22103	BALLARD* Closed Suction System for Adults, 14 F, DSE	09/30/2020
2210	BALLARD* Closed Suction System for Adults, 14 F, DSE	09/30/2020