

EU Declaration of Conformity

Legal Manufacturer: AVANOS Medical, Inc.
5405 Windward Parkway
Alpharetta, GA 30004
United States of America
Single Registration Number (SRN): US-MF-000016181

Authorised Representative: Avanos Medical Belgium BV
Leonardo Da Vincilaan 1
1930 Zaventem
Belgium
Single Registration Number (SRN): BE-AR-000002191

GMDN Code and Term: 62581 – Nasogastric tube holder, intranasal

EMDN Code and Term: G02020199 Nasogastric Intestinal Tubes – Other

Identification of Device(s):

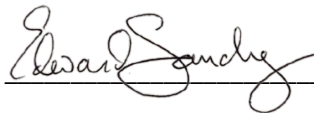
Product Code(s)	Trade Name and Description	Product Family	Basic UDI-DI:	Risk Class	Annex VIII Classification Rule	Start Date of EU MDR CE Mark
26-008	Avanos* CORGRIP* SR NG/NI Tube Retention System, 8 FR	CORGRIP* SR NG/NI Tube Retention System	0350770CSRS10619RV	I	Rule 5	10-May-2024
26-010	Avanos* CORGRIP* SR NG/NI Tube Retention System, 10 FR	CORGRIP* SR NG/NI Tube Retention System	0350770CSRS10619RV	I	Rule 5	10-May-2024
26-012	Avanos* CORGRIP* SR NG/NI Tube Retention System, 12 FR	CORGRIP* SR NG/NI Tube Retention System	0350770CSRS10619RV	I	Rule 5	10-May-2024
26-014	Avanos* CORGRIP* SR NG/NI Tube Retention System, 14 FR	CORGRIP* SR NG/NI Tube Retention System	0350770CSRS10619RV	I	Rule 5	10-May-2024
26-016	Avanos* CORGRIP* SR NG/NI Tube Retention System, 16 FR	CORGRIP* SR NG/NI Tube Retention System	0350770CSRS10619RV	I	Rule 5	10-May-2024
26-018	Avanos* CORGRIP* SR NG/NI Tube Retention System, 18 FR	CORGRIP* SR NG/NI Tube Retention System	0350770CSRS10619RV	I	Rule 5	10-May-2024

Intended Purpose: The CORGRIP* SR Nasogastric/Nasointestinal (NG/NI) Tube Retention System is indicated for use with enteral feeding tubes of 8 FR and greater and NG decompression, suction and drainage tubes up to 18 FR to prevent inadvertent removal or displacement of the tubes for adult patients.

Conformity Assessment Procedure: MDR 2017/745 Article 52[7]: Conformity Assessment Based on a Quality Management System and Technical Documentation as per Annex II and III.

This EU Declaration of Conformity is issued according to Annex IV under the sole responsibility of AVANOS Medical, Inc. The device(s) contained within this declaration is/are in conformance with EU 2017/745 Medical Device Regulations.

Identification of the person authorized to sign for and on behalf of Avanos Medical, Inc.:

Signature:  _____

Name: Edward Sanchez

Title: Principal, Regulatory Affairs

Date: 16-May-2024
(DD-MMM-YYYY)

Place of Issue: AVANOS Medical, Inc.
5405 Windward Parkway
Alpharetta, GA 30004 (USA)