AVANOS

5405 Windward Parkway
Alpharetta, GA 30004
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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:

EC REP

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

Identification of the device(s):

Product Code(s)	Trade Name and Description	Product Family	Basic UDI-DI:	Risk Class	Classification Rule	Start Date of EU MDR CE Mark
ATAS-6-NSB	Avanos ANCORIS*Tube Anchor Set, 6Fr	Accessory – Tube Securement	0350770ATAS19011GJ	Class I nm, ns	Annex VIII, Rule 1 Non-Invasisve Devices	27Dec2022
ATAS-8-NSB	Avanos ANCORIS*Tube Anchor Set, 8Fr					
ATAS-10-NSB	Avanos ANCORIS*Tube Anchor Set, 10Fr					
ATAS-12-NSB	Avanos ANCORIS*Tube Anchor Set, 12Fr					
ATAS-14-NSB	Avanos ANCORIS*Tube Anchor Set, 14Fr					

Intended Purpose:

The AVANOS* ANCORIS* Tube Anchor Set is a Single-Use Medical Device indicated for use in pediatric and adult patients to externally secure tubes from 6 FR to 14 FR. The device is intended to be used by or under the direction of trained clinicians and professional caregivers.

Conformity Assessment Procedure:	Annex IV
Notified Body:	Not applicable, Class I non-measuring, non-sterile
EU Certificate(s) issued:	Not applicable, Class I non-measuring, non-sterile

This EU Declaration of Conformity is issued under the sole responsibility of AVANOS Medical, Inc. The device(s) contained within this declaration 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: Erin Walker

Name: Erin Walker

Title: Associate Director, Regulatory Affairs

Date: 27-DEC-2022

(DD-MMM-YYYY)

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