

EC Declaration of Conformity

Product description : PEG Kit Accessories

Product Codes : See attached Annex (product list)

UMDNS Code: 11677 (Enteral Feeding Kits)

GMDN Code: 35419 (Gastrostomy tube)

Legal Manufacturer (Place of Issue): Avanos Medical, Inc
5405 Windward Parkway
Alpharetta, Georgia (GA) 30004, USA

EU Authorized Representative: Avanos Medical Belgium BVBA
Leonardo Da Vincilaan 1
1930 Zaventem
Belgium

Product Standards: BS EN 1615 2000
ISO 80369-3 2013*

Start of CE: See attached Annex (product list)

Conformity Assessment Route: Annex II

Device Classification: Class IIa (as per Rule 2 of Annex IX)

CE certificate number: CE 711145

Notified Body: BSI Netherlands (2797)

Quality System Certificate: FM 702907

We hereby declare that the above mentioned devices comply with the provisions of the European 93/42/EEC Council Directive on Medical Devices

All supporting documentation is retained at the premises of Halyard Health, Inc. This Declaration of Conformity is issued under the sole responsibility of Avanos Medical, Inc and is valid for the products listed on the attached product list in their original, unmodified packaging

Authorized Signature



Name Thomas Kozma
Title Director, Regulatory Affairs
Avanos Medical, Inc
Date 10 July 2019

Annex (Product List)

This declaration of conformity is issued under the sole responsibility of Halyard Health, Inc , and is valid for the products listed on the attached product list in their original, unmodified packaging

Product Code	Product Description	Start of CE Mark
0135-14	MIC* PEG Replacement Feeding Adapter, 14 Fr	07/10/2019
0135-20	MIC* PEG Replacement Feeding Adapter, 20 Fr	07/10/2019
0135-24	MIC* PEG Replacement Feeding Adapter, 24 Fr	07/10/2019
0136-14	MIC* PEG Replacement Feeding Adapter, 14 Fr	07/10/2019
0136-20	MIC* PEG Replacement Feeding Adapter, 20 Fr	07/10/2019
0136-24	MIC* PEG Replacement Feeding Adapter, 24 Fr	07/10/2019
0137-14	MIC* PEG Replacement Adapter, 14 Fr	07/10/2019
0137-20	MIC* PEG Replacement Adapter, 20 Fr	07/10/2019
0137-24	MIC* PEG Replacement Adapter, 24 Fr	07/10/2019
8135-14	MIC* PEG Replacement Feeding Adapter with ENFit™ Connectors, 14 Fr	07/10/2019
8135-20	MIC* PEG Replacement Feeding Adapter with ENFit™ Connectors, 20 Fr	07/10/2019
8135-24	MIC* PEG Replacement Feeding Adapter with ENFit™ Connectors, 24 Fr	07/10/2019