EC Design Examination Certificate

Certificate No.:	Project No.:	Valid Until
10000447991-PA-NA-IND Rev 1.0	PRJC-584672-2018-PRC-IND	27-May-2024

This is to certify that :

PTCA BALLOON CATHETERS – SEMI COMPLIANT & NON COMPLIANT

Manufactured by:

Advanced MedTech Solutions Private Limited

P-21-22, 25-26, 34-35, GIDC Manjusar,
Taluka-Savli, District-Vadodara,
Gujarat – 391775, INDIA

Has been assessed with respect to:

examination of the design of the product as described in Annex II section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 06 April 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	**Description**	**Issue Date**
0.0	Original Certificate	2021-03-25
1.0	**Editorial changes**	**2021-04-06**

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
• ADVA GLIDE - PTCA Balloon Catheter - Semi Compliant • NC ADVA GLIDE - PTCA Balloon Catheter - Non Compliant	III	47732
Short description of the Medical Device:		
ADVA GLIDE is a Rapid Exchange Balloon Catheter – Semi Compliant, designed to be used in Percutaneous Transluminal Coronary Angioplasty (PTCA) to dilate a stenotic coronary artery by controlled inflation of a distensible balloon(s) at its distal tip. It contains double lumen for balloon inflation and guide wire movement. Available in various sizes and intended for the dilatation of small, narrowed, or obstructed coronary arteries or bypass grafts stenosis and for post-dilatation of a balloon-expandable stent. This is a single-use device and sterilized by EtO. NC ADVA GLIDE is a Rapid Exchange Balloon Catheter – Non Compliant, designed to be used in Percutaneous Transluminal Coronary Angioplasty (PTCA) to dilate a stenotic coronary artery by controlled inflation of a distensible balloon(s) at its distal tip. It contains double lumen for balloon inflation and guide wire movement. Available in various sizes and intended for the dilatation of small, narrowed, or obstructed coronary arteries or bypass grafts stenosis and for post-delivery expansion of a balloon-expandable stent in the coronary arteries. This is a single-use device and sterilized by EtO.		

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended change of the products detailed above and the Notified Body will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System. When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate