Device Description Document
NB Stent
DES system
Revision 1.5

NB Stent ™

Note for this exercise you will need the MDR and a copy of MDCG 2021-24.

Participants need not stress too much of the technical aspects of the device chosen here, but the application of the requirements of MDR Annex II Part 1.

If you are not familiar with the device do not worry - the point of this exercise is to look at the gaps vs. the section of the Annex and determine if more elaboration is needed or if something is missing.

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1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

1.1.1 General description of the device

The NB stent is a class III Drug eluting stent that is used in the heart to treat coronary artery disease.

1.1.1.1 Intended Use.

The NB stent is to be used on patients with coronary artery disease .

1.1.1.2 Indications for use.

The NB stent is indicated for improving arterial luminal diameter due to the presence of lesions in native coronary arteries that have a diameter of 2.50 to 3.5 mm. It is indicated for patients who have symptoms heart disease, Myocardial infarction, Angina(both stable and unstable).

1.1.1.3 Intended users.

The intended users are Cardiologists.

1.1.1.4 Intended Use Environment.

The intended use Environment is in a hospital operating theatre.

1.1.2 Product Identification, Product codes UDI.

Complete list of the various configurations/variants of the device that are intended to be made available on the market.

EMDN code P07040201

#	Product Code	UDI DI	Nominal diameter inner MM	Stent length mm	Drug dose (ug)
1	NBS-1	**123458abc**	**2.25**	**8**	**125**
2	NBS-2	**23456abc**	**2.50**	**8**	**125**
3	NBS-3	**25874def**	**2.50**	**38**	**300**
4	NBS-4	**2358wex**	**3.00**	**8**	**326**
5	NBS-5	**1258764g**	**3.00**	**38**	**380**
6	NBS-6	**356871trc**	**3.50**	**8**	**391**
7	NBS-7	**258795hgt**	**3.50**	**38**	**425**

8	NBS-8	**008812345**	**4.00**	**8**	**430**
9	NBS-9	**00887526**	**4.00**	**38**	**460**

1.1.3 Intended patient population and medical conditions.

The intended patient population is patients who are eligible for coronary artery stenting.

1.1.4 Principals of Operation and Device Mode of Action

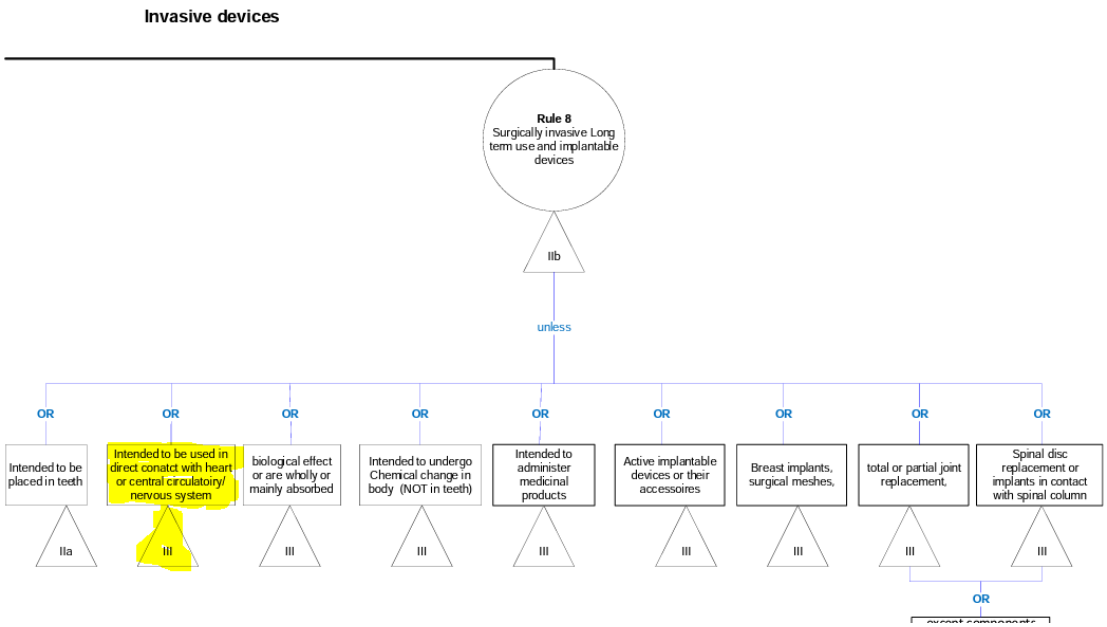
The NB stent is a bare metal coronary stent coated with a PLGA polymer that contains a coated everolimus drug. The device is designed to release the drug to prevent cell proliferation and prevent narrowing of the vessel (restenosis).

1.1.5 Rationale for the qualification of the product as a device.

The NB stent is a drug eluting stent and therefore a medical device.

1.1.6 Device Risk Class and Classification Rule Justification

NB Stent is a Class III device according to Annex VIII, Chapter III, Rule 8 of Regulation (EU) 2017/745.



1.1.7 Explanation of any novel features

There are no novel features in the NB stent.

1.1.8 Accessories or other devices to be used with the device.

The following medical device accessories are intended to be used in combination with the device:

1	A guiding catheter with a minimum inner diameter of 0.056”
1	Pre-dilatation balloon catheter
1	10-20 ml syringe
1	0.014-inch guidewire
1	Rotating hemostatic valve
1	Inflation device
1	Three-way stopcock

Additionally, the following products which are not medical devices are required to be used within the procedure:

1000 IU	Heparin per 500 cc Normal Saline (HepNS)
N/A	Contrast medium diluted 1: 1 with normal saline

1.1.9 Key Functional elements

The NB stent consists of the following key components.

- A Platinum Chromium stent (PtCR).
- Everolimus incorporated into a biodegradable Poly(lactic-co-glycolic acid) PLGA coating that is coated abluminally onto the stent.
- A stent delivery system comprising of a semi compliant balloon referred to as Summit™.

All of which are in direct or indirect contact with the human body.

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1.1.10 Technical Specifications

- Stent Delivery system

Catheter design	Rapid Exchange
Usable shaft length	142 cm ± 3 cm
Proximal shaft design	Hypotube
Proximal shaft coating	PTFE
Proximal shaft profile	2.1 F / 0.0274” / 0.70 mm (with PTFE coating)
Shaft markers placement	85 cm ± 3 cm and 95 cm ± 2 cm from tip
Distal shaft profile	2.6 F / 0.034"/ 0.86 mm
Lesion entry profile	0.017" / 0.43 mm
Balloon material	(Pebax) 72D
Balloon compliance	Semi-compliant
Balloon folding	Tri-Fold
Balloon overhang	0.5 mm on either side (3.0 x 20 mm balloon, for reference)
Balloon cone	30 degrees
Radiopaque markers	2 swaged platinum/iridium marker bands
Length of balloon markers	0.5/0.9mm (distal/proximal)
Nominal pressure	9 atm /811 kPa for all models
Rated Burst Pressure	16 atm / 1621 kPa (2.25 - 3.0 mm)
14 atm / 1418 kPa (3.5 - 4.0 mm)	
Guiding catheter compatibility	5 F for all models (min. guiding catheter ID of 0.056” / 1.42mm)
Guide wire compatibility	0.014"/ 0.36 mm for all models (max. guidewire OD of 0.014” / 0.336mm)
Hydrophilic coating	W-II coating – covers the catheter shaft and tip, with the exception of the balloon itself (up to 50cm to proximal shaft from tip)
Hub	Luer taper and thread must meet EN ISO 80369-7 requirements

- Stent Platform Specification

Stent material	PTCR
Stent platform	NB stent
Strut design	Corrugated rings
Link design	“S” connector and straight connector
Strut thickness	SV – 0.0033”/0.084mm
MV – 0.0035”/0.088mm	

Segment length	1.4 mm (for reference)
Stent crowns	SV- 6 crowns (2.25 mm - 3.0 mm)
MV- 9 crowns (3.5 mm - 4.0 mm)	
Stent crossing profile (max)	0.044" / 1.12 mm
Flexibility	Very good
Radiopacity	Good
MRI Compatibility	MR Conditional

1.1.11 Reference to previous generations

NB stent is the latest generation of the NB stent system and has previous CE marking approval under MDD certificate number 12345abcd.

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