

Government of Pakistan Ministry of National Health Services Regulations & Coordination Drug Regulatory Authority of Pakistan

Sr. No. ____1586



FORM-8

[see rule 15(5)]

CERTIFICATE OF ENLISTMENT OR REGISTRATION OF A MEDICAL DEVICE OR ACCESSORY OR COMPONENT FOR LOCAL MANUFACTURE

Licence No.

ELM-0018

Date of issue:

15/09/2020

F.No:

12-1/2018-MD

M/s N-ovative Health Technologies (NHT) Pvt. Ltd

National University of Science and Technology (NUST), Sector H-12, Islamabad

The medical device as per details given below has been registered or enlisted under the DRAP Act, 2012 and the rules made there-under subject to the conditions appearing hereinafter:

Enlistment/ Registration No.	Name of medical device or	Brief description	Class	Shelf life
NO.	accessory			, ,
	or component			
(1)	(2)	(3)	(4)	(5)
MDMR-000080	REJUVENATE Cobalt-Chromium	Indicated for used in coronary	D	03 Years
	Bare Metal Balloon	occlusive disease. Indicated to be implanted in a coronary artery to		* * * * * * * * * * * * * * * * * * *
	Expandable Coronary Stent System [Sterile	maintain luminal patency and improve luminal diameter in	35.86 N	
	Single Use]	patients with symptomatic atherosclerotic heart disease.		
		Sterile, single-use. [Codes & Sizes at Annex-A]		
MDMR-000081	VASOGLIDE Rapid	Flexible tube designed to be used	D	03 Years
	Exchange PTCA Angioplasty Balloon	in percutaneous transluminal coronary angioplasty (PTCA) to	5a 5a	
	Catheter [Sterile Single Use]	dilate stenotic coronary artery by controlled inflation of a distensible		
		balloon(s) at its distal tip. May also be intended for pre-or	8	
		post-dilatation of a balloon-expandable stent in		·
		coronary arteries. Sterile, single-use	±	
s		[Codes & Sizes at Annex-A]	40	Dr. Shazanfar Ali Khar Dr. Shazanfar Ali Khar Dr. Shazanfar Ali Khar On Shazanfar Ali Khar On Shazanfar Shakan
				Drug Regulatory Alumbar Service, Drug Regulation & Coordination Regulation & Coordination Regulation & Covernment of Pakistan Government of Pakistan



Name and complete address of manufacturer:

M/s N-ovative Health Technologies (NHT) Pvt. Ltd

National University of Science & Technology (NUST) Sector H-12, Islamabad.

- 2. This enlistment/registration shall be valid for a period of five years from the date mentioned above unless earlier suspended or cancelled.
- 3. The name shall be changed in case it has resemblance with already enlisted/registered medical device.
- 4. This enlistment/registration is subject to the conditions specified in the DRAP Act, 2012 and the rules made there-under.

Renewal Date: 13/09/2025



ANNEXURE - (A)

<u>REJUVENATE Cobalt-Chromium Bare Metal Balloon Expandable Coronary Stent System (Sterile Single Use)</u> Sizes (mm):

 2.0×08 , 2.0×12 , 2.0×16 , 2.0×18 , 2.0×22 , 2.0×26 , 2.0×30 , 2.5×08 , 2.5×12 , 2.5×16 , 2.5×18 , 2.5×22 , 2.5×26 , 2.5×30 , 3.0×08 , 3.0×12 , 3.0×16 , 3.0×18 , 3.0×22 , 3.0×26 , 3.0×30 , 3.5×08 , 3.5×12 , 3.5×16 , 3.5×18 , 3.5×22 , 3.5×26 , 3.5×30 , 4.0×08 , 4.0×12 , 4.0×16 , 4.0×18 , 4.0×22 , 4.0×26 , 4.0×30

VASOGLIDE Rapid Exchange PTCA Angioplasty Balloon Catheter (Sterile Single USe)

Sizes (mm):

 $2.0 \times 12, 2.0 \times 16, 2.0 \times 20, 2.0 \times 22, 2.0 \times 26, 2.0 \times 30, 2.0 \times 34, 2.5 \times 12, 2.5 \times 16, 2.5 \times 20, 2.5 \times 22, 2.5 \times 26, 2.5 \times 30, 2.5 \times 34, 3.0 \times 12, 3.0 \times 16, 3.0 \times 20, 3.0 \times 22, 3.0 \times 26, 3.0 \times 30, 3.0 \times 34, 3.5 \times 12, 3.5 \times 16, 3.5 \times 20, 3.5 \times 22, 3.5 \times 26, 3.5 \times 30, 3.5 \times 34, 4.0 \times 12, 4.0 \times 16, 4.0 \times 20, 4.0 \times 22, 4.0 \times 26, 4.0 \times 30, 4.0 \times 34$

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