



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Design-Examination Certificate

No. 17 0529 CN/NB

issued for manufacturer

Sahajanand Laser Technology Ltd.

**A-8 G. I. D. C Electronic Estate, Sector-25, Gandhinagar-382016,
Gujarat, India**

in accordance with requirements of

Directive 93/42/EEC

on medical devices, Annex II (4)

for the following product category(ies):


Drug Eluting Coronary stent with and without delivery system

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with MDD Annex II. The design of the devices conforms to the requirements of this Directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

Valid from: 2017-12-19
Valid until: 2022-11-09
First Issued: 2017-11-10
Revision: a



Date: 2017-12-19


RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



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Annex to EC Design-Examination Certificate

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Product:

Name: Drug Eluting Coronary Stent (CoCr) with and without delivery system

Trade name(s): FlexyRap


Model(s): FlexyRap® Cobalt Chromium Rapamycin Eluting Coronary Stent with and without Delivery System

Class: III

GMDN: 58771



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Detailed specification of product Drug eluting Stent (CoCr.) with delivery system


Product	Brand name	Variation in size (mm)
Cobalt Chromium Rapamycin Eluting Coronary Stent System (CoCr L605) Model: FlexyRap®	Stent	FlexyRap® Diameter: 2.25; 2.5; 2.75; 3.0; 3.5; 4.0; 4.5 Length: 7, 10, 13, 15, 17, 20, 24, 28, 33, 38, 42, 45 (±0.5mm up to 26mm and ±0.7mm beyond 26mm)
	Delivery System	PTCA Balloon Catheter (Vector®) Diameter = 2.25; 2.5; 2.75; 3.0; 3.5; 4.0; 4.5 mm (± 0.1mm) The length of the applicable PTCA catheter shall be +1 mm (±0.2 mm) of the stent length for Sizes up to 42 and +0.5 mm (±0.2mm) of the stent length for sizes above it. Rapid exchange length: 25 cm ± 2.5 cm Shaft length: 143±3 cm Min. guide wire diameter: 0.014" Min. guiding catheter ID: 5F Nominal pressure: 6 bar Related burst pressure: 16 bar for diameter ≤ 3.00 mm 14 bar for diameter ≥ 3.50 mm

Detailed specification of product Drug eluting Stent (CoCr.) without delivery system

Product	Brand name	Variation in size (mm)
Cobalt Chromium Rapamycin Eluting Coronary Stent (CoCr L605)	FlexyRap®	Diameter: 1.8 Length: 7, 10, 13, 15, 17, 20, 24, 28, 33, 38, 42, 45 (±0.5mm up to 26mm and ±0.7mm beyond 26mm)



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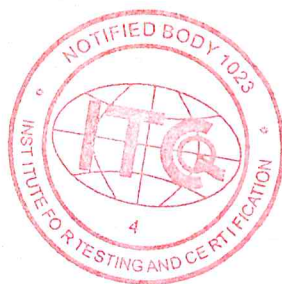
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Certificate History:

Revision	Date	Reference Number	Action
---	2017-11-10	803601860A	Certification
a	2017-12-DD	803601860B	Typo correction



Date: 2017-12-19
Revision: a

Paul Uš
RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023