



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

EC Certificate - Full Quality Assurance System No. 17 0528 QS/NB

The quality system of manufacturer

Sahajanand Laser Technology Ltd.

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

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Drug Eluting Coronary stent with and without delivery system

Bare Metal Coronary stent with and without delivery system

PTCA Balloon Catheter

The Notified Body No. 1023 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) 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 Certificate No. 17 0528 QS/NB

issued for manufacturer:

Sahajanand Laser Technology Ltd.
A-8 G. I. D. C Electronic Estate, Sector-25, Gandhinagar-382016,
Gujarat, India

Product(s):

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

Trade name(s): EasyRap
MovyRap
TwinRap

Model(s): EasyRap® Stainless Steel Rapamycin Eluting Coronary Stent with and without Delivery System
MovyRap® Stainless Steel Rapamycin Eluting Coronary Stent with and without Delivery System
TwinRap® Stainless Steel Rapamycin Eluting Coronary Stent with and without Delivery System

Class: III
GMDN: 58771

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

Date: 2017-12-19
Revision: a




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Name: **Bare Metal Coronary Stent (S. S.) with and without delivery system**

Trade name(s): MovyStar
EasyFlex
Sector
TwinFlex

Model(s): MovyStar® Stainless Steel Coronary Stent with and without Delivery System
EasyFlex® Stainless Steel Coronary Stent with and without Delivery System,
other trade name Sector® Stainless Steel Coronary Stent with and without Delivery System
TwinFlex® Stainless Steel Coronary Stent with and without Delivery System

Class: III
GMDN: 53616


Name: **PTCA Balloon Catheter**

Trade name(s): Vector® PTCA Balloon Catheter
Tracker® PTCA Balloon Catheter

Model(s): ---
Class: III
GMDN: 47732

Date: 2017-12-19
Revision: a




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Name: **Bare Metal Coronary Stent (CoCr) with and without delivery system**

Trade name(s): FlexyStar
Passager
HexaPro


Model(s): FlexyStar® Cobalt Chromium Coronary Stent with and without Delivery System,
other trade name Passagerr® Cobalt Chromium Coronary Stent with and without Delivery System
HexaPro® Cobalt Chromium Coronary Stent with and without Delivery System

Class: III

GMDN: 53616



Date: 2017-12-19
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issued for manufacturer:

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

Facility(ies):

Sahajanand Laser Technology Ltd.


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

Certificate History:

Revision	Date	Reference Number	Action
---	2017-11-10	803601860A	Certification
a	2017-12-19	803601860B	Adding new products + typo correction



Date: 2017-12-19
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