



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Sahajanand Laser Technology Ltd

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

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Device Family	Device	GMDN Code	Class
PTCA Balloon Catheter	Vector, Tracker, Vector Pro, Ripper	47732	III
	Vector NC, Vector Axial, Waive, Impeller	47732	III

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no. 545047 MR2
Certificate unique ID 170753742
Effective date 2020-05-29
Expiry date 2024-05-26
Frankfurt am Main 2020-05-29

DQS Medizinprodukte GmbH

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Dr. Thomas Feldmann
Head of Certification Body

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.