



# EC Design Examination Certificate

## Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

### Sahajanand Laser Technology Ltd

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

that the design of the following device(s)

**PTCA Balloon Catheter in the variants as listed in annex**

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.

This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 545047 MR2. Changes to the approved design are subject to further approval by the Notified Body.

**Basis of examination:** TCF/004/04/02 rev 04 dated 07-11-2019

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

**Examination report:** 422\_18e\_Report\_TFR\_Sahjanand Laser\_PTCA Balloon Catheter\_V3.docx 411.18e Version: 6.0 dated 2020-04-19

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no. 545047 MRA

Certificate unique ID 170768637

Effective date 2020-05-29

Expiry date 2024-05-26

Frankfurt am Main 2020-05-29

### DQS Medizinprodukte GmbH

Sigrid Uhlemann  
Managing Director

Dr. Thomas Feldmann  
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,  
Tel. +49 (0) 69 95427-300, [medical.devices@dqs-med.de](mailto:medical.devices@dqs-med.de)

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



**Annex to certificate**  
**Certificate registration No.: 545047 MRA**  
**Certificate unique ID: 170768637**  
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<b>Device Family</b>	<b>Device</b>	<b>GMDN Code</b>
PTCA Balloon Catheter	Vector, Tracker, Vector Pro, Ripper	47732
	Vector NC, Vector Axial, Waive, Impeller	47732