



Notified Body No 1023  
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.  
Zlín, Czech Republic – [www.itczlin.cz](http://www.itczlin.cz)

# EC CERTIFICATE

No. 16 0062 QS/NB

Issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 54/2015 (Collection of Laws) certifies that the product – medical device of Class III, type

## **Sirolimus Coated Balloon Catheter**

**Brand name: Magic Touch**

*(For detailed specification refer to Annex of this Certificate, page 1)*

manufactured by company

## **Envision Scientific Private Limited**

**Corporate office: Office 1~3, Silver Palm II, Near Sneh Milan Garden, Kadampalli, Nanpura, Surat - 395 001 Gujarat, INDIA**

**Factory: Plot No. C1B-108 Ichchhapore GIDC, Industrial Estate, Bhatpore, Sachin - Hazira Road, Surat - 394510, Gujarat, INDIA**

is manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2 of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5, of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803601950/2016, which is enclosed to this Certificate.

### *Condition of this Certificate use and related information:*

- 1. It applies only to the quality system maintained in the manufacture of the above referenced models of the medical devices and it does not substitute the design or type-examination procedures.*
- 2. The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 11<sup>th</sup> February 2021 at the latest.*
- 3. The Certificate validity is conditioned by positive results of surveillance audits.*
- 4. After receiving of the complementary EC Design-Examination Certificate related to the above referenced models, and fulfilling of the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE marking followed by the number of the Notified Body according to this example:*

**CE 1023**



*RNDr. Radomír Čevelík*

RNDr. Radomír Čevelík

Representative of the Notified Body No. 1023

Issued in Zlín, on 12<sup>th</sup> February 2016



## Annex to EC Certificate No. 16 0062 QS/NB

Issued for the company:

### Envision Scientific Private Limited

Corporate office: Office 1~3, Silver Palm II, Near Sneh Milan Garden, Kadampalli,  
Nanpura, Surat - 395 001 Gujarat, INDIA

Factory: Plot No. C1B-108 Ichchhapore GIDC, Industrial Estate,  
Bhatpore, Sachin - Hazira Road, Surat - 394510, Gujarat, INDIA

### List of the medical devices covered by the EC certificate:

Name of Product: Magic Touch Sirolimus Coated Balloon Catheter  
Variant: -  
Item: See Reference Number  
Category: Non Active non implantable device  
Class: III  
GMDN: 10698

Dia/Length	10 mm	15 mm	20 mm	25 mm	30 mm	35 mm	40 mm
1.50 mm	CMT15010	CMT15015	CMT15020	CMT15025	CMT15030	CMT15035	CMT15040
2.00 mm	CMT20010	CMT20015	CMT20020	CMT20025	CMT20030	CMT20035	CMT20040
2.25 mm	CMT22510	CMT22515	CMT22520	CMT22525	CMT22530	CMT22535	CMT22540
2.50 mm	CMT25010	CMT25015	CMT25020	CMT25025	CMT25030	CMT25035	CMT25040
2.75 mm	CMT27510	CMT27515	CMT27520	CMT27525	CMT27530	CMT27535	CMT27540
3.00 mm	CMT30010	CMT30015	CMT30020	CMT30025	CMT30030	CMT30035	CMT30040
3.25 mm	CMT32510	CMT32515	CMT32520	CMT32525	CMT32530	CMT32535	CMT32540
3.50 mm	CMT35010	CMT35015	CMT35020	CMT35025	CMT35030	CMT35035	CMT35040
4.00 mm	CMT40010	CMT40015	CMT40020	CMT40025	CMT40030	CMT40035	CMT40040



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RNDr. Radomir Čevelík  
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