

EC Design Examination Certificate: Certificate CN20/123458

## APT Medical Inc.

Room 601, Building B, Tongfang Information Port, No.11 Langshan Road,  
Nanshan District, 518057, Shenzhen, P.R. China

Device Identification:  
**Triguy™ Mapping Catheter**

Intended Purpose of Device:  
**Sterile mapping catheter for cardiac electrogram recording  
and cardiac stimulation during diagnostic electrophysiology studies.**

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on Medical Devices, Annex II, Section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device  
has been examined and, based on the evidence submitted, it is considered that the device conforms  
to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system  
to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 24 April 2020 until 13 May 2024  
Issue 1. Certified since 13 May 2019  
and first certified by SGS Belgium NV since 24 April 2020

Certification is based on reports numbered CN/CSX 15336

Addenda to that report have been issued on the following dates:

Addendum Date  
17/01/2020

Reason for Addendum  
Change of manufacturer's address

Authorised by



**SGS Belgium NV, Notified Body 1639**

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