

EC Design Examination Certificate: Certificate CN19/41134

APT Medical Inc.

No. 009, Xiangxiang Road, Xiangxiang Economic Development Zone,
Xiangxiang City, Hunan, 411400, P.R. China

Device Identification:
Hydrophilic Guidewire

Intended Purpose of Device:
Sterile hydrophilic guidewire used to guide a catheter into the desired coronary or peripheral anatomical location during interventional procedure.

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 21 May 2021 until 24 May 2024

Issue 2

Certification is based on reports numbered CN/CSX 15264
Addenda to that report have been issued on the following dates:

Addendum Date
N/A

Reason for Addendum
N/A

Authorised by

Global Medical Devices Head of Notified Body

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