# EC-CERTIFICATE

**(Full quality assurance system)**

This is to certify that the company

## Laboratoires FILL-MED

2-4 rue de Lisbonne
75008 Paris
France

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:

NCTF 135, NCTF 135 HA and M-HA 10 (class 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.

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| Certificate registration no. | 339178 MR2 |
| Certificate unique ID | 170712942 |
| Effective date | 2018-12-27 |
| Expiry date | 2021-09-18 |
| Frankfurt am Main | 2018-12-27 |

**DQS Medizinprodukte GmbH**

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