ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod Lisem 129, 171 02 Praha 8 - Troja

# EC CERTIFICATE
# FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 160037 Z

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **SARL NOVA LIGHTSYSTEMS**
**LA FERME DE VERDOLETTE LES DANJAUDS, 13610 LE PUY SAINTE REPARADE, France**

for design, manufacturing and final inspection of medical device(s)

**Steril accessories for endoscopic use such as:**
**• Biopsy Forceps-Class IIa**
**• Dilation Balloon-Class IIa**
**See annex**

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **405205-01 of 21.11.2014; 503501-04/01 of 12.07.2016**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 29.07.2016 with validity until 20.10.2019
**The validity of this Certificate is limited until: 20.10.2019**

29.07.2016

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

elektrotechnický zkušební ústav ezú -1- Pod Lisem 129, 171 02 Praha 8 - Troja
Stamp

*CER/MED160037Z*

503501-04

| Description | Référence Nova Light Systems |
|---|---|
| **BIOPSY FORCEPS - Class IIa** | |
| Trachéo-bronchial / Smooth | **CJ-PPT-18-110** |
| Trachéo-bronchial / Notch / | **CJ-PPTC-18-110** |
| Trachéo-bronchial / Smooth / With needle | **CJ-PPT-18-110-A** |
| Paediatric / Smooth / | **CJ-PPT-18-160** |
| Adult Standard / Smooth / | **CJ-PAT-23-160** |
| Adult Standard / Smooth / With needle | **CJ-PAT-23-160-A** |
| Adult Standard / Notch / | **CJ-PATC-23-160** |
| Adult Standard / Notch / With needle | **CJ-PATC-23-160-A** |
| Adult Standard / Smooth / | **CJ-PAT-23-230** |
| Adult Standard / Smooth / With needle | **CJ-PAT-23-230-A** |
| Adult Standard / Notch / | **CJ-PATC-23-230** |
| Adult Standard / Notch / With needle | **CJ-PATC-23-230-A** |

| **Dilation Balloon - Class IIa** | |
|---|---|
| Dilation Balloon | **CJ-JHY-BD-06-40-250** |
| Dilation Balloon | **CJ-JHY-BD-08-40-250** |
| Dilation Balloon | **CJ-JHY-BD-10-40-250** |
| Dilation Balloon | **CJ-JHY-BD-12-60-250** |
| Dilation Balloon | **CJ-JHY-BD-14-60-250** |
| Dilation Balloon | **CJ-JHY-BD-18-80-250** |
| Dilation Balloon | **CJ-JHY-BD-20-80-250** |
| Achalasia balloon | **CJ-JHY-BD-30-80-90** |
| Achalasia balloon | **CJ-JHY-BD-35-80-90** |

End of the list

elektrotechnický zkušební ústav
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