

# ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



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

Pod lisem 129/2, 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 180073

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 **Aesthetic Group**  
**ZA de la Gobette, 60540 Puisieux le Hauberger, France**

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

**Medical devices single use as: cannulas, punches and curettes – sterile, class IIa**

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. **802680-01/01 of 17.12.2018**.

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 18.12.2018 with validity until 17.12.2023  
**The validity of this Certificate is limited until: 17.12.2023**

18.12.2018

Prague

Mgr. Miroslav Sedláček  
Head of Certification Body



802680-01

**CANULES DE LIPOTRANSFERT / LIPOTRANSFER CANNULAS – Class IIa – MD0102 :**

Référence	Description
CP32301	Canule de prélèvement de graisse / Cannula for fat harvesting
CP42301	Canule de prélèvement de graisse / Cannula for fat harvesting
CP3015 (LP0201-10)	Canule de prélèvement de graisse / Cannula for fat harvesting
CP3023	Canule de prélèvement de graisse / Cannula for fat harvesting
CP17853HS	Canule de prélèvement de graisse / Cannula for fat harvesting
CP161053HS	Canule de prélèvement de graisse / Cannula for fat harvesting
CP141253HS	Canule de prélèvement de graisse / Cannula for fat harvesting
CP141506HS	Canule de prélèvement de graisse / Cannula for fat harvesting
CP141253HV	Canule de prélèvement de graisse / Cannula for fat harvesting
CP31503M	Canule de prélèvement de graisse / Cannula for fat harvesting
CP32303M	Canule de prélèvement de graisse / Cannula for fat harvesting
CP42303M	Canule de prélèvement de graisse / Cannula for fat harvesting
CP32303T	Canule de prélèvement de graisse / Cannula for fat harvesting
CP42303T	Canule de prélèvement de graisse / Cannula for fat harvesting
CP141304H	Canule de prélèvement de graisse / Cannula for fat harvesting
CP30154H	Canule de prélèvement de graisse / Cannula for fat harvesting
CP141256HMP	Canule de prélèvement de graisse / Cannula for fat harvesting
CP35176H	Canule de prélèvement de graisse / Cannula for fat harvesting
CP122007H	Canule de prélèvement de graisse / Cannula for fat harvesting
CP123007H	Canule de prélèvement de graisse / Cannula for fat harvesting
CP141508H	Canule de prélèvement de graisse / Cannula for fat harvesting
CP301524H	Canule de prélèvement de graisse / Cannula for fat harvesting
CP302324H	Canule de prélèvement de graisse / Cannula for fat harvesting
CP301512R	Canule de prélèvement de graisse / Cannula for fat harvesting
CP30153S	Canule de prélèvement de graisse / Cannula for fat harvesting
CP1690V	Canule de prélèvement de graisse / Cannula for fat harvesting
CP16150V	Canule de prélèvement de graisse / Cannula for fat harvesting
CP1490V	Canule de prélèvement de graisse / Cannula for fat harvesting
CP14150V	Canule de prélèvement de graisse / Cannula for fat harvesting
CP142012	Canule de prélèvement de graisse / Cannula for fat harvesting
CP142512	Canule de prélèvement de graisse / Cannula for fat harvesting
CP143012	Canule de prélèvement de graisse / Cannula for fat harvesting
CP112012	Canule de prélèvement de graisse / Cannula for fat harvesting
CP112512	Canule de prélèvement de graisse / Cannula for fat harvesting
CP113012	Canule de prélèvement de graisse / Cannula for fat harvesting
CF10790	Canule d'injection de graisse / Cannula for fat injection
CF12790	Canule d'injection de graisse / Cannula for fat injection
CF14790	Canule d'injection de graisse / Cannula for fat injection
CF15790	Canule d'injection de graisse / Cannula for fat injection
CF16890	Canule d'injection de graisse / Cannula for fat injection
CF151090	Canule d'injection de graisse / Cannula for fat injection
CF201090 (LP0401-10)	Canule d'injection de graisse / Cannula for fat injection
CF201590 (LP0402-10)	Canule d'injection de graisse / Cannula for fat injection
CF202290	Canule d'injection de graisse / Cannula for fat injection
CF27990	Canule d'injection de graisse / Cannula for fat injection
CF271590	Canule d'injection de graisse / Cannula for fat injection
CF301590	Canule d'injection de graisse / Cannula for fat injection



<b>Référence</b>	<b>Description</b>
CF301990	Canule d'injection de graisse / Cannula for fat injection
CF401990	Canule d'injection de graisse / Cannula for fat injection
CF15745	Canule d'injection de graisse / Cannula for fat injection
CF151045	Canule d'injection de graisse / Cannula for fat injection
CF201545	Canule d'injection de graisse / Cannula for fat injection
CF202345	Canule d'injection de graisse / Cannula for fat injection
CFL201502LE	Canule d'injection de graisse / Cannula for fat injection
CF0965290	Canule d'injection de graisse / Cannula for fat injection
CF141590SP	Canule d'injection de graisse / Cannula for fat injection
CF142090SP	Canule d'injection de graisse / Cannula for fat injection
CF142590SP	Canule d'injection de graisse / Cannula for fat injection
CF142090CSP	Canule d'injection de graisse / Cannula for fat injection
CF142590CSP	Canule d'injection de graisse / Cannula for fat injection
CF111590SP	Canule d'injection de graisse / Cannula for fat injection
CF112090SP	Canule d'injection de graisse / Cannula for fat injection
CF112590SP	Canule d'injection de graisse / Cannula for fat injection
CF112090CSP	Canule d'injection de graisse / Cannula for fat injection
CF112590CSP	Canule d'injection de graisse / Cannula for fat injection
CF1420BF	Canule d'injection de graisse / Cannula for fat injection
CF1425BF	Canule d'injection de graisse / Cannula for fat injection
CF1120BF	Canule d'injection de graisse / Cannula for fat injection
CF1125BF	Canule d'injection de graisse / Cannula for fat injection
CR30155OD (LP0501-01)	Canule d'injection de graisse / Cannula for fat injection
MF11180	Canule de prélèvement de graisse / Cannula for fat harvesting
MF11182	Canule d'injection de graisse / Cannula for fat injection
MF11183	Canule d'injection de graisse / Cannula for fat injection
MF11184	Canule d'injection de graisse / Cannula for fat injection
CPOE1660	Canule de transfert autologue de graisse / Cannula for autologous fat transfer
CPOE18100	Canule de transfert autologue de graisse / Cannula for autologous fat transfer
CPOE3155	Canule de transfert autologue de graisse / Cannula for autologous fat transfer
CPOE3195	Canule de transfert autologue de graisse / Cannula for autologous fat transfer
CPOE3275	Canule de transfert autologue de graisse / Cannula for autologous fat transfer
CPOE3300	Canule de transfert autologue de graisse / Cannula for autologous fat transfer
CPOE35150	Canule de transfert autologue de graisse / Cannula for autologous fat transfer
AL 701	Canule Crépine de lyse / Crepine de lyse cannula
AL 702	Canule Crépine de lyse / Crepine de lyse cannula
CI16150	Canule de Klein / Klein cannula
CI18100	Canule de Klein / Klein cannula
CI21100	Canule de Klein / Klein cannula
CI21150 (LP0101-10)	Canule de Klein / Klein cannula
CI21250 (LP0102-10)	Canule de Klein / Klein cannula
CI25150	Canule de Klein / Klein cannula
CI25250	Canule de Klein / Klein cannula
CI25300	Canule de Klein / Klein cannula
991 011	Canule d'irrigation / Irrigating cannula



**CANULES DE LIPOSUCCION / LIPOSUCTION CANNULAS – Class IIa– MD0102 :**

Référence	Description
LC 31302	Canule de liposuccion / Liposuction cannula
LC 32302	Canule de liposuccion / Liposuction cannula
LC 42302	Canule de liposuccion / Liposuction cannula
LC 42802	Canule de liposuccion / Liposuction cannula
LC 52802	Canule de liposuccion / Liposuction cannula
LC 62802	Canule de liposuccion / Liposuction cannula
LC 31303	Canule de liposuccion / Liposuction cannula
LC 32303 (LP0301-05)	Canule de liposuccion / Liposuction cannula
LC 42303	Canule de liposuccion / Liposuction cannula
LC 42803 (LP0302-05)	Canule de liposuccion / Liposuction cannula
LC 52803 (LP0303-05)	Canule de liposuccion / Liposuction cannula
LC 62803	Canule de liposuccion / Liposuction cannula
LC 31304H	Canule de liposuccion / Liposuction cannula
LC 32804H	Canule de liposuccion / Liposuction cannula
LC 313024H	Canule de liposuccion / Liposuction cannula
LC 328024H (LP0304-05)	Canule de liposuccion / Liposuction cannula
LC 428024H (LP0305-05)	Canule de liposuccion / Liposuction cannula
LC 31503HVS	Canule de liposuccion / Liposuction cannula
LC 32303HVS	Canule de liposuccion / Liposuction cannula
LC 32303M (LP0306-05)	Canule de liposuccion / Liposuction cannula
LC 42803M (LP0307-05)	Canule de liposuccion / Liposuction cannula
LC 52803M (LP0308-05)	Canule de liposuccion / Liposuction cannula

**MICRO-CANULES DE COMPLEMENT / FILLING MICRO -CANNULAS – Class IIa – MD0102 :**

Référence	Description
MI1825	Micro-canule de comblement / Filling Micro-cannula
MI1850	Micro-canule de comblement / Filling Micro-cannula
MI1870	Micro-canule de comblement / Filling Micro-cannula
MI18110	Micro-canule de comblement / Filling Micro-cannula
MI2145/L	Micro-canule de comblement / Filling Micro-cannula
MI2170/L	Micro-canule de comblement / Filling Micro-cannula
MI2240/L	Micro-canule de comblement / Filling Micro-cannula
MI2250/L	Micro-canule de comblement / Filling Micro-cannula
MI2270/L	Micro-canule de comblement / Filling Micro-cannula
MI2290/L	Micro-canule de comblement / Filling Micro-cannula
MI2340/L	Micro-canule de comblement / Filling Micro-cannula
MI2350/L	Micro-canule de comblement / Filling Micro-cannula
MI2370/L	Micro-canule de comblement / Filling Micro-cannula
MI2438/L	Micro-canule de comblement / Filling Micro-cannula
MI2450/L	Micro-canule de comblement / Filling Micro-cannula
MI2525 /L	Micro-canule de comblement / Filling Micro-cannula
MI2540/L	Micro-canule de comblement / Filling Micro-cannula
MI2550/L	Micro-canule de comblement / Filling Micro-cannula
MI2625/L	Micro-canule de comblement / Filling Micro-cannula
MI2638/L	Micro-canule de comblement / Filling Micro-cannula
MI2650/L	Micro-canule de comblement / Filling Micro-cannula
MI2725/L	Micro-canule de comblement / Filling Micro-cannula



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<b>Référence</b>	<b>Description</b>
MI2738/L	Micro-canule de comblement / Filling Micro-cannula
MI2750/L	Micro-canule de comblement / Filling Micro-cannula
MI3025/N	Micro-canule de comblement / Filling Micro-cannula
CT14100	Micro-canule de comblement / Filling Micro-cannula
CT1870	Micro-canule de comblement / Filling Micro-cannula
CT1880	Micro-canule de comblement / Filling Micro-cannula
CT1950	Micro-canule de comblement / Filling Micro-cannula
CT1970	Micro-canule de comblement / Filling Micro-cannula
CT2040	Micro-canule de comblement / Filling Micro-cannula
CT2050	Micro-canule de comblement / Filling Micro-cannula
CT2070	Micro-canule de comblement / Filling Micro-cannula
CT2150	Micro-canule de comblement / Filling Micro-cannula
MI1870KR	Micro-canule de comblement / Filling Micro-cannula
MI1890KR	Micro-canule de comblement / Filling Micro-cannula
MI18110KR	Micro-canule de comblement / Filling Micro-cannula
MI2140KR	Micro-canule de comblement / Filling Micro-cannula
MI2170KR	Micro-canule de comblement / Filling Micro-cannula
MI2250KR	Micro-canule de comblement / Filling Micro-cannula
MI2270KR	Micro-canule de comblement / Filling Micro-cannula
MI2290KR	Micro-canule de comblement / Filling Micro-cannula
MI2350KR	Micro-canule de comblement / Filling Micro-cannula
MI2370KR	Micro-canule de comblement / Filling Micro-cannula
MI2438KR	Micro-canule de comblement / Filling Micro-cannula
MI2450KR	Micro-canule de comblement / Filling Micro-cannula
MI2525KR	Micro-canule de comblement / Filling Micro-cannula
MI2538KR	Micro-canule de comblement / Filling Micro-cannula
MI2550KR	Micro-canule de comblement / Filling Micro-cannula
MI2625KR	Micro-canule de comblement / Filling Micro-cannula
MI2638KR	Micro-canule de comblement / Filling Micro-cannula
MI2650KR	Micro-canule de comblement / Filling Micro-cannula
MI2725KR	Micro-canule de comblement / Filling Micro-cannula
MI2740KR	Micro-canule de comblement / Filling Micro-cannula
MI2750KR	Micro-canule de comblement / Filling Micro-cannula
MI3025KR	Micro-canule de comblement / Filling Micro-cannula
MI17100KRM	Micro-canule de comblement / Filling Micro-cannula
MI1870KRM	Micro-canule de comblement / Filling Micro-cannula
MI1890KRM	Micro-canule de comblement / Filling Micro-cannula
MI1950KRM	Micro-canule de comblement / Filling Micro-cannula
MI2050KRM	Micro-canule de comblement / Filling Micro-cannula
MI2170KRM	Micro-canule de comblement / Filling Micro-cannula
MI1838KRSP	Micro-canule de comblement / Filling Micro-cannula
MI1850KRSP	Micro-canule de comblement / Filling Micro-cannula
MI1870KRSP	Micro-canule de comblement / Filling Micro-cannula
MI2038KRSP	Micro-canule de comblement / Filling Micro-cannula
MI2050KRSP	Micro-canule de comblement / Filling Micro-cannula
MI2150KRSP	Micro-canule de comblement / Filling Micro-cannula
CTW1950	Micro-canule de comblement / Filling Micro-cannula
CTW1970	Micro-canule de comblement / Filling Micro-cannula
CTW2050	Micro-canule de comblement / Filling Micro-cannula
CTW2150	Micro-canule de comblement / Filling Micro-cannula

*J. Maláček*



<b>Référence</b>	<b>Description</b>
XTW2150	Micro-canule de comblement / Filling Micro-cannula
XTW2170	Micro-canule de comblement / Filling Micro-cannula
XTW2250	Micro-canule de comblement / Filling Micro-cannula
XTW2270	Micro-canule de comblement / Filling Micro-cannula
XTW2550	Micro-canule de comblement / Filling Micro-cannula
XTW2740	Micro-canule de comblement / Filling Micro-cannula
SP12150	Micro-canule de comblement / Filling Micro-cannula
SP14120	Micro-canule de comblement / Filling Micro-cannula
SP14150	Micro-canule de comblement / Filling Micro-cannula
SP16100	Micro-canule de comblement / Filling Micro-cannula
SP16120	Micro-canule de comblement / Filling Micro-cannula
SP16150	Micro-canule de comblement / Filling Micro-cannula
SP1880	Micro-canule de comblement / Filling Micro-cannula
SP18100	Micro-canule de comblement / Filling Micro-cannula
SP18120	Micro-canule de comblement / Filling Micro-cannula
SP2050	Micro-canule de comblement / Filling Micro-cannula
SP2230	Micro-canule de comblement / Filling Micro-cannula
SP2250	Micro-canule de comblement / Filling Micro-cannula
SP2270	Micro-canule de comblement / Filling Micro-cannula
SP2540	Micro-canule de comblement / Filling Micro-cannula
SP2550	Micro-canule de comblement / Filling Micro-cannula
SP2560	Micro-canule de comblement / Filling Micro-cannula
SP2725	Micro-canule de comblement / Filling Micro-cannula

**KIT CANULE + AIGUILLE / CANNULA + NEEDLE KIT – Classe IIa – MD0102 :**

<b>Référence</b>	<b>Description</b>
KIT 1/N	Kit MI 1870 + Aiguille/Needle 18G x40 mm
KIT 2/L	Kit MI 2270 + Aiguille/Needle 22G x25 mm
KIT 3/L	Kit MI 2550 + Aiguille/Needle 25G x16 mm
KIT 4/L	Kit MI 2740 + Aiguille/Needle 27G x13 mm
KIT 5/L	Kit MI 3025 + Aiguille/Needle 30G x13 mm
KIT 6/L	Kit MI 2250 + Aiguille/Needle 22G x25 mm
KIT 7/L	Kit MI 2540+ Aiguille/Needle 25G x16 mm
KIT 8/L	Kit MI 2290+ Aiguille/Needle 22G x25 mm
KIT 9/L	Kit MI 2240+ Aiguille/Needle 22G x25 mm
KIT 13/L	Kit MI 2525 + Aiguille/Needle 25G x16 mm
KIT 14/L	Kit MI 2538 + Aiguille/Needle 25G x16 mm
KIT 15/L	Kit MI 2550 + Aiguille/Needle 25G x16 mm
KIT 16/L	Kit MI 2725 + Aiguille/Needle 27G x13 mm
KIT 17/L	Kit MI 2738 + Aiguille/Needle 27G x13 mm
KIT 18/L	Kit MI 2750 + Aiguille/Needle 27G x13 mm
KIT 19/N	Kit MI 2240KR + Aiguille/Needle 22G x 25 mm
KIT 21/L	Kit MI 2525KR + Aiguille/Needle 25G x 16 mm
KIT 22/L	Kit MI 2538KR + Aiguille/Needle 25G x 16 mm
KIT 24/L	Kit MI 2725KR + Aiguille/Needle 27G x13 mm
KIT 25/L	Kit MI 2738KR + Aiguille/Needle 27G x13 mm
KIT 26/L	Kit MI 2750KR + Aiguille/Needle 27G x13 mm
KIT 29/L	Kit MI 18110 + Aiguille/Needle 18G x40
MI2170KE	Kit MI2170KE + Aiguille/Needle 21G x 40 mm



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Référence	Description
MI2250KE	Kit MI2250KE + Aiguille/Needle 22G x 25 mm
MI2550KE	Kit MI2550KE + Aiguille/Needle 25G x 16 mm
MI2740KE	Kit MI2740KE + Aiguille/Needle 27G x 13 mm
MI2170KS	Kit MI2170KS + Aiguille/Needle 21G x 40 mm
MI2250KS	Kit MI2250KS + Aiguille/Needle 22G x 25 mm
MI2550KS	Kit MI2550KS + Aiguille/Needle 25G x 16 mm
MI2740KS	Kit MI2740KS + Aiguille/Needle 27G x 13 mm

**DISPODERM – Class IIa– MD0106 :**

Référence	Description
PB030	Punch à biopsie / Biopsy punch Ø 0.30 mm
PB050	Punch à biopsie / Biopsy punch Ø 0.50 mm
PB075	Punch à biopsie / Biopsy punch Ø 0.75 mm
PB100	Punch à biopsie / Biopsy punch Ø 1.00 mm
PB125	Punch à biopsie / Biopsy punch Ø 1.25 mm
PB150	Punch à biopsie / Biopsy punch Ø 1.50 mm
PB200	Punch à biopsie / Biopsy punch Ø 2.00 mm
PB250	Punch à biopsie / Biopsy punch Ø 2.50 mm
PB300	Punch à biopsie / Biopsy punch Ø 3.00 mm
PB350	Punch à biopsie / Biopsy punch Ø 3.50 mm
PB400	Punch à biopsie / Biopsy punch Ø 4.00 mm
PB500	Punch à biopsie / Biopsy punch Ø 5.00 mm
PB600	Punch à biopsie / Biopsy punch Ø 6.00 mm
PB800	Punch à biopsie / Biopsy punch Ø 8.00 mm
CD2	Punch dermatologique / Dermal punch Ø 2.00 mm
CD3	Punch dermatologique / Dermal punch Ø 3.00 mm
CD4	Punch dermatologique / Dermal punch Ø 4.00 mm
CD5	Punch dermatologique / Dermal punch Ø 5.00 mm
CD7	Punch dermatologique / Dermal punch Ø 7.00 mm

End of the list


