

## Medical Device Laboratory

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Delebio, February 1<sup>st</sup> , 2013

**To whom it may concern**

### **CERTIFICATE OF AUTHORISATION:**

Distributorship for **MDL's** products.

This is to certify that,

**ECOCHIMIE Ltd.**  
**5/1, Cuza Voda str.**  
**2060MD, Chisinau,**  
**Republic of Moldova**  
**Tel/fax +373(22)-52-34-32, 52-34-22**  
**infoecochimie@gmail.com**  
**info@ecochimie.md**  
**www.ecochimie.md**

is our authorised distributor for the complete **MDL's** product line.

This company is able to provide competitive and professional sales information, to take parts in tenders and after-sales service of **MDL's** products to their customers in his area and to participate in tenders on behalf of **MDL srl** Company.

**MDL srl Company**  
**Dr. Marcello Dell'Oca**  
**President**

**M.D.L. s.r.l.**  
Via Tavani 1/A - 23014 DELEBIO (SO)  
P.IVA: 00656810140



# CERTIFICATO N° 063SGQ04

CERTIFICATE N° 063SGQ04

Si certifica che il  
*this is to certify that*

Sistema di Gestione per la Qualità  
*Quality Management System*

messo in atto da  
*implemented by*

**M.D.L. S.r.l.**

Via Tavani, 1/a - IT 23014 DELEBIO (SO)

nella Sede Operativa di  
*Operative Unit*

Via Tavani, 1/a - IT 23014 DELEBIO (SO)

è conforme alla norma  
*is in compliance with the standard*

**UNI EN ISO 9001-2015 (ISO 9001-2015)**

per i seguenti Processi  
*concerning the following kinds of Processes*

Progettazione, fabbricazione e vendita di aghi per biopsie, siringhe odontoiatriche, aghi per lavaggio canalari, aghi per anestesia loco-regionale, aghi per anestesia spinale, aghi per aspirazione cito-istologica, aghi per alcolizzazione, aghi per localizzazione mammaria, kit per toracentesi e paracentesi, aghi per laparoscopia, cannule per liposuzione, set e kit per galattografia, aghi per donazione sangue. Produzione conto terzi di componenti e accessori per dispositivi medici di cui sopra. Progettazione e fabbricazione di prodotti e componenti per medicina veterinaria. Gestione della progettazione e della produzione, immissione in commercio a proprio nome di dispositivi medici attivi per elettrostimolazione.

*Design, manufacture and sale of biopsy needles, dental syringes, needles for canalar washing, needles for loco-regional anesthesia, needles for spinal anesthesia, needles for cyto-histological aspiration, needles for alcoholization, needles for mammarian nodules localization, kits for paracentesis and thoracentesis, needle for laparoscopy, liposuction cannula, kits and sets for galactografy, blood donor needles. Manufacture for contractors of components and accessories of medical devices as above description. Design and production of components for veterinarian medicine. Management of design and manufacturing, placing on the market under his own name of active medical devices for electrostimulation*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.

*This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.*

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana

*In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language*

IL PRESIDENTE

THE PRESIDENT

  
Prof. Dr. Carlo Tribuno



Data di Prima Emissione  
*First Issue Date*

1998-07-24

Data di Rinnovo  
*Renewal Date*

2017-12-20

Data di Scadenza  
*Expiration Date*

2020-12-19

Settore IAF 17 - 14 - 19



SGQ N° 023A PRD N° 122B  
SGA N° 020D ISP N° 075E  
PRS N° 097C

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*

# CERTIFICATO N° 063DM05

CERTIFICATE N° 063DM05

Si certifica che il

*this is to certify that*

## Sistema di Gestione per la Qualità

*Quality Management System*

messo in atto da

*implemented by*

**M.D.L. S.r.l.**

Via Tavani, 1/a - IT 23014 DELEBIO (SO)

nella Sede Operativa di

*Operative Unit*

Via Tavani, 1/a - IT 23014 DELEBIO (SO)

è conforme alla norma

*is in compliance with the standard*

**UNI CEI EN ISO 13485:2016 (ISO 13485-2016)**

per i seguenti Processi

*concerning the following kinds of Processes*

Progettazione, fabbricazione e vendita di aghi per biopsie, siringhe odontoiatriche, aghi per lavaggio canalari, aghi per anestesia loco-regionale, aghi per anestesia spinale, aghi per aspirazione cito-istologica, aghi per alcolizzazione, aghi per localizzazione mammaria, kit per toracentesi e paracentesi, aghi per laparoscopia, cannule per liposuzione, set e kit per galattografia, aghi per donazione sangue.

Produzione conto terzi di componenti e accessori per dispositivi medici di cui sopra.

Gestione della progettazione e della produzione, immissione in commercio a proprio nome di dispositivi medici attivi per elettrostimolazione

*Design, manufacture and sale of biopsy needles, dental syringes, needles for canalar washing, needles for loco-regional anesthesia, needles for spinal anesthesia, needles for cyto-histological aspiration, needles for alcoholization, needles for mammarian nodules localization, kits for paracentesis and thoracentesis, needle for laparoscopy, liposuction cannula, kits and sets for galactography, blood donor needles. Manufacture for contractors of components and accessories of medical devices as above description.*

*Management of design and amanufacturing, placing on the market under his own name of active medical devices for electrostimulation*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.

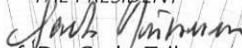
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IL PRESIDENTE

THE PRESIDENT



Prof. Dr. Carlo Tribuno

Data di Prima Emissione

*First Issue Date*

1998-07-24

Data di Rinnovo

*Renewal Date*

2017-12-20

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*Expiration Date*

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SGQ N° 023A PRD N° 122B  
SGA N° 020D ISP N° 075E  
PRS N° 097C

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*

**CERTIFICATE N° 166-02-00-DM**  
(in compliance with Annex V of the Directive 93/42/EEC)

**ITALCERT**

certifies that the

Production Quality Assurance System  
applied for the manufacture and final inspection  
of "Medical Devices" - MD -  
by the manufacturer

**M.D.L. S.r.l.**

via Tavani, 1/a - 23014 DELEBIO (SO) - ITALY

in the headquarters located in

via Tavani, 1/a  
23014 DELEBIO (SO) - ITALY

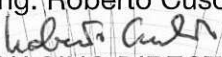
complies with the requirements stated in

**Directive 93/42/EEC - Annex V**

and authorizes the manufacturer to mark



in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC  
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito  
  
MANAGING DIRECTOR

First Issue date  
2011-04-29

Renewal date  
2018-12-20

Expire date  
2023-12-19



**Annex 1 to Certificate n° 166-02-00-DM**

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**Surgically Invasive Medical Devices for Transient Use and accessories  
(class IIa)****PJ $\alpha$  $\beta$  $\chi$  $\delta$  $\epsilon$  $\phi$  $\eta$ XXYY $\mu$** 

Disposable needle for bone biopsy with external Trap system, for bone marrow, sternal, iliac aspiration. PJ= Needle family field

 $\alpha$ = variable field for Trap: *omissis* (no Trap), T (if  $\delta$ = *omissis*, standard Trap) $\beta$ = variable field for lateral holes: *omissis* (no holes), E (5 holes) $\chi$ = variable field for the handling: *omissis* (PJ version), K1 (tsunami version), K2 (Jamblue version with razor sharpening) $\delta$ = variable field for Trap version: *omissis* (no Trap or standard Trap), D (double spoon version), G (serrated spoon), F (wire version), L (spring version), S (second stylet blunt) $\epsilon$ = variable field for Vise®: *omissis* (absent), R (present) $\phi$ = variable field for conical tip cannula version: *omissis* (conical tip cannula), V (non conical tip cannula) $\gamma$ = variable field for tip version: *omissis* (fish mouth type), H (5-tip diamond), P (razor sharpening), C (16° Chiba tip) $\eta$ = variable field la controcannula: *omissis* (absent), Zn (Controcannula a punta 90°, n =1 to 10) XX= Gauge

YY= Length [cm]

 $\mu$ = variable field for color: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green) Cannula outer diameter: from 7 G to 18 G.

Length: from 50 mm to 250 mm

Sampling, injection and infusion, introduction of devices and synthesis methods versions: codes PJ, PJE, PJEK1, PJK2

**PJE $\alpha$ XXYY $\mu$** 

Disposable needle for explant and diamond sharpening with lateral holes. PJE= Needle family field

 $\alpha$ = variable field: *omissis* (standard), R (Vise®), K1 (version without neither lateral holes nor swaged, Chiba sharpening), S (second blunt stylet, inner cannula with close tip and lateral holes) $\mu$ = variable field for colour: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green) XX= Gauge

YY= Length [cm]

Cannula outer diameter: from 7 G to 18 G

Length: from 50 mm to 250 mm

**SDXXYY**

Disposable needle for bone biopsy with inserted trapping system (PJ handle). Bone marrow, sternal and iliac aspiration needle.

XX= Gauge

YY= Length [cm]

Cannula outer diameter: from 7 G to 18 G

Length: from 50 mm to 250 mm



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**PS $\alpha\beta\chi\delta$ XXYY $\mu$** 

Disposable needle for bone biopsy with inserted trapping system (PJ handle). Bone marrow, sternal and iliac aspiration needle.

PS= Needle family field

 $\alpha$ = variable field for Trap version: *omissis* (serrated Trap), Hn (close tip Trap with lateral holes: n:1= 6 holes; n:2 = 8 holes; n:3 = 10 holes; n:4 = 12 holes). If the Trap has Hn the cannula has (2\*(n. holes of the Trap) +1) holes $\beta$ = variable field for *Vise@*: *omissis* (absent), R (present) $\chi$ = variable field for cannula tip version: *omissis* (fish mouth type), D (5-tip diamond version) $\delta$ = variable field for extra stylet: *omissis* (no extra stylet), Mn with n:1 = same stylet of the needle; n:2 = blunt stylet; n:3 = double blunt stylets

XX= Gauge

YY= Length [cm]

 $\mu$ = variable field for colour: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green) Cannula outer diameter: from 7 G to 18 G

Cannula length: from 50 mm to 250 mm

**PI $\alpha\beta\chi\delta\epsilon$ XXYY/ZZ $\mu$** 

Disposable needle for bone biopsy, bone marrow, sternal and iliac aspiration. PI= Needle family field

 $\alpha$ = variable field for handling: *omissis* (PI version), P (light type version), L (anatomic handle version mdl, T type) $\beta$ = variable field for lateral holes: *omissis* (absent), E (2 holes) $\chi$ = variable field for comfort handle accessories: *omissis* (absent), Q (present – rubbery ball) $\delta$ = variable field for the plastic ferrule: *omissis* (present), G (absent) $\epsilon$ = variable field for *Vise@*: *omissis* (absent), R (present) XX= Gauge

YY= minimum length [mm] ZZ=

maximum length [mm]

 $\mu$ = variable field for colour: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green) Cannula outer diameter: from 14G to 25G

Cannula length: from 10 mm to 300 mm

Version for explant with side holes: PIE code. Version for sampling, injection and infusion, introduction of devices and synthesis methods: PI, PIE, PIP, PIPE, PIL codes.

**PM $\alpha\beta\chi$ XXYY $\mu$** 

Disposable manual needle for soft tissue biopsy. PM= Needle family field

 $\alpha$ = variable field for ecobright version: *omissis* (standard version), E (ecobright version) $\beta$ = variable field for *Vise@*: *omissis* (absent), R (present) XX= Gauge

YY= Length [cm] (if length 114 mm: length YYY [mm])

 $\mu$ = variable field for colour: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green) Cannula outer diameter: from 11G to 22G

Cannula length: from 50 mm to 500 mm



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**PD $\alpha\beta\chi\delta\epsilon\phi\gamma$ XXYY $\mu$** 

Disposable needle for semi-automatic guillotine soft tissue biopsy. PD= Needle family field

 $\alpha$ = variable field for cannula detachment: *omissis* (available), 0 (not available) $\beta$ = variable field for coaxial: *omissis* (absent), PP (present) $\chi$ = variable field for separated stylet: *omissis* (absent), P (present) $\delta$ = variable field stylet tip: *omissis* (lancet), T (Trocar) $\epsilon$ = variable field for ecobright: *omissis* (standard version), E (ecobright version) $\phi$ = variable field for MRI material: *omissis* (standard version), MR (MRI version) $\gamma$ = variable field for Vise@: *omissis* (absent), R (present) XX= Gauge

YY= Length [cm]

 $\mu$ = variable field for colour: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green) Cannula outer diameter: from 12G to 22G

Cannula length: from 50mm to 500mm

Version for sampling, injection and infusion, introduction of devices and synthesis methods: PD code.

**MG $\alpha\beta\chi\delta\epsilon\phi\gamma\eta$ XXYY $\mu$** 

Disposable needle for automatic biopsy gun. MG=

Needle family field

 $\alpha$ = variable field for handling type: *omissis* (Magnum Bard gun type), K1 (Magnum and Palium gun type), P (Promag gun type) $\beta$ = variable field for spacer: *omissis* (present), N (absent) $\chi$ = variable field for coaxial: *omissis* (absent), C (present) $\delta$ = variable field for stylet tip: *omissis* (lancet), T (Trocar) $\epsilon$ = variable field for ecobright: *omissis* (standard version), E (ecobright version) $\phi$ = variable field - MGK1 only – for MRI material: *omissis* (standard material), MR (MRI material) $\gamma$ = variable field - MGK1 only – for cover: *omissis* (absent), V (present) $\eta$ = variable field for Vise@: *omissis* (absent), R (present) XX= Gauge

YY= Length [cm]

 $\mu$ = variable field for colour: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green) Cannula outer diameter: from 12G to 22 G

Cannula length: from 50 mm to 500 mm MGK1

version with coaxial: MGC.

Version for sampling, injection and infusion, introduction of devices and synthesis methods: MG, MGK1, MGP, MGPC, MGC, MGT, MGTC, MGPT, MGTCPC codes.

**VE $\alpha\beta\chi\delta\epsilon\phi$ XXYY $\mu$** 

Disposable needle for automatic biopsy gun. VE=

Needle family field

 $\alpha$ = variable field for handling: *omissis* (standard version, Promag type), S (FastGun type 1), P (FastGun type 2), J (Pajunk type), M (Medax type), B (BIP type), D (MD type) $\beta$ = variable field for spacer: *omissis* (present), N (absent) $\chi$ = variable field for coaxial: *omissis* (absent), C (present) $\delta$ = variable field for stylet tip: *omissis* (lancet), T (Trocar) $\epsilon$ = variable field for ecobright: *omissis* (standard version), E (ecobright version) $\phi$ = variable field for Vise@: *omissis* (absent), R (present)

XX= Gauge

YY= Length [cm]

 $\mu$ = variable field for colour: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green) Cannula outer diameter: from 12G to 22 G

Cannula length: from 50 mm to 500 mm



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**PT $\alpha\beta\chi\delta\epsilon\phi\gamma$ XXYYY**

Needle for sampling, injection and infusion, introduction of devices and synthesis methods (PT codes). Coaxial introducer needle for introducing components (codes PT0).

PT= Needle family field

$\alpha$ = variable field for stylet: *omissis* (present), 0 (absent)

$\beta$ = variable field for stylet plug: *omissis* (rounded with luer-lock), Q (quick release)

$\chi$ = variable field for stylet tip: *omissis* (Trocar), F (25° razor tip), P (lancet tip)

$\delta$ = variable field for cannula tip: *omissis* (blunt), C (25° Chiba tip)

$\epsilon$ = variable field for ecobright: *omissis* (standard version), E (ecobright version)

$\phi$ = variable field for MRI: *omissis* (standard version), M (MRI material version)

$\gamma$ = variable field for Vise@: *omissis* (absent), R (present) XX= Gauge

YYY= Length [mm]

Cannula outer diameter: from 08G to 25G

Cannula length: from 20 mm to 500 mm

**PA $\alpha\beta$ XXYY**

Set for aspirated histological and cytological biopsies according to Menghini method. PA= Needle family field

$\alpha$ = variable field for ecobright: *omissis* (standard version), E (ecobright version)

$\beta$ = variable field for Vise@: *omissis* (absent), R (present) XX= Gauge

YYY= Length [cm]

Cannula outer diameter: from 14G to 22G

Cannula length: from 50 mm to 350 mm

**PC $\alpha\beta\chi\delta\epsilon\phi$ XXYY**

Needle for aspirated histological and cytological biopsies according to Menghini modified method. PC= Needle family field

$\alpha$ = variable field for handling: *omissis* (100 ml syringe), 0 (DE type)

$\beta$ = variable field - PC0 only – for coaxial: *omissis* (absent), C (present)

$\chi$ = variable field for stylet tip: *omissis* (Trocar), F (Franseen type), T (lancet tip)

$\delta$ = variable field for Vise@: *omissis* (absent), R (present)

$\epsilon$ = variable field for ecobright: *omissis* (standard version), E (ecobright version)

$\phi$ = variable field for MRI: *omissis* (standard material), M (MRI material) XX= Gauge

YY= Length [cm]

Cannula outer diameter: from 14G to 25G

Cannula length: from 50 mm to 300 mm

**PE $\alpha\beta\chi$ XXYY**

Chiba needle for cytohistological aspiration and introduction (PEM code). Chiba needle for cytological aspiration and soft tissues histological biopsy (PEF, PEW codes).

PE= Needle family field

$\alpha$ = variable field for cannula tip: M (Menchetti type), F (Franseen type), W (Westcott type)

$\beta$ = variable field for ecobright: *omissis* (standard version), E (ecobright version)

$\chi$ = variable field for Vise@: *omissis* (absent), R (present) XX= Gauge

YY= Length [cm]

Cannula outer diameter: from 16G to 26G

Cannula length: from 50 mm to 300 mm



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**LPXXYY $\alpha\beta\beta\chi$** 

Sterile disposable cannula for lipoaspiration. Cannula for collection, injection and infusion, introduction of devices and synthesis methods.

LP= Needle family field XX=

Outer diameter [mm] YY=

Length [cm]

 $\alpha$ = variable field for joint: R1 (plastic joint), R2 (reinforced joint) $\beta$ = variable field tip version (according to technical drawing) $\chi$ = variable field for electrical insulation: *omissis* (absent), C (present) Cannula outer

diameter: from 0,5mm to 8mm

Length: from 50mm to 500mm

**32Z2000/ 32Z2002/ 32Z2004/ 32Z2020/ 32Z2022/ 32Z2024/ 32Z2030/ 32Z2032/ 32Z2034/ 32Z2036/  
32Z2038/ 32Z2039/ 32Z2040/ 32Z20YY**

Disposable needle for gingival biopsy (AG1). Outer diameter from 3mm to 7mm.

**32Z2006/ 32Z2007/ 32Z2008/ 32Z2009**

Disposable needle for guided gingival biopsy (AG2). Outer diameter 4.0mm, 4.9mm, 6.0mm, 5.1mm.

**32Z2026/ 32Z2027**

Disposable needle for linear gingival biopsy (AG3). Length 45mm. Thickness 0.63mm. Cutting edge diameter 2mm.

**TY $\alpha\beta\chi\delta\epsilon\phi\gamma$ XXYY $\mu$** 

Themy automatic gun for soft tissue biopsy. TY=

Needle family field

 $\alpha$ = variable field for sampling mechanism: *omissis* (guillotine type), K (guillotine type with double key), Q (rotational, guillotine), F (rotational, full core) $\beta$ = variable field for the notch length: *omissis* (20mm), S (10mm) $\chi$ = variable field for coaxial: *omissis* (absent), C (present) $\delta$ = variable field for the stylet tip: *omissis* (lancet), T (Trocar) $\epsilon$ = variable field for ecobright: *omissis* (standard version), E (ecobright version) $\phi$ = variable field for MRI: *omissis* (standard material version), MR (MRI material version) $\gamma$ = variable field for Vise®: *omissis* (absent), R (present)

XX= Gauge

YY= Length [cm]

 $\mu$ = variable field for colour: *omissis* (standard), B (blue), Y (yellow), P (pink), G (green)

Cannula outer diameter: from 12G to 22G

Length: from 30mm to 500 mm

**AE $\alpha\beta$ XXYY $\mu$** 

Electro neuro stimulation needle. AE=

Needle family field

 $\alpha$ = variable field for the tip: T (lancet tip, lancet 16°), Q (Quinke tip, lancet 30°), C (Chiba tip), Y (lancet 20° tip), P (pencil point) $\beta$ = variable field for the procedure: R (E.N.S. technique, safety Vise® not available), S (subcutaneous technique, safety Vise® not available), M (hybrid technique E.N.S. and Ultrasound, safety Vise® included), MN (Ultrasound technique, safety Vise® included)

XX= gauge

YYY= Length [mm]

 $\mu$ = variable field for colour: *omissis* (standard), W (white), Y (yellow), P (pink), G (green)

Diameter: from 14G to 30G

Length: from 10mm to 200mm



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**PB $\alpha\beta\chi\delta$ XXYY**

Chiba needle for cytological aspiration and substances injection, LLDU MDL cone. PB= Needle family field

 $\alpha$ = variable field standard version o MRI (M) $\beta$ = variable field for stylet plug: *omissis* (TMC), R (Quick release) $\chi$ = variable field for tip type: *omissis*, T, Q, U $\delta$ = variable field for extension cord: *omissis* (absent), P (present) XX= Gauge

YY= Length [cm]

Diameter: from 14G to 30G

Length: from 30mm to 500mm

**PBUTXXYY**

Chiba needle with introducer for cytological aspiration, villocentesis, aspiration of amniotic fluid and injection of substances.

XX= Gauge

YY= Length [cm]

Diameter: from 14G to 30G

Length: from 30mm to 500mm

**PBL $\alpha$ XXYY**

Chiba needle for cyto-histological aspirated biopsy and liquid injection with extension cord and stylet. PBL= Needle family field

 $\alpha$ = variable field standard version or without sandblasting treatment (N) XX= Gauge

YY= Length [cm]

Diameter: from 14G to 30G

Length: from 30mm to 500mm

**PB4 $\alpha\beta$ XXYY**

Solid substrate deposition needle. PB4= Needle family field

 $\alpha$ = variable field standard version or A, B, C, D, E, F version $\beta$ = variable field for Vise® (R) XX= Gauge

YY= Length

Diameter: from 14G to 26G

Length: from 30mm to 500mm

**PZ $\alpha\beta$ XXYY**

Galactography procedure Kit/set. PZ= Needle family field

 $\alpha$ = variable field: version with dilators (1 to 6), 1mL syringe, needle (Z); version with two dilators, 1mL syringe, extension cord and needle (Y); set version with extension cord and final slim needle and junction (X); $\beta$ = variable field for geometry: straight (D) o bent (C) XX= Gauge

YY= Length [mm]

Diameter: from 18G to 30G

Length: from 20mm to 40mm

**ACXXYY**

Root canal cleaning needle. AC= Needle family field XX= Gauge or diameter YY= Length [mm]

Diameter: from 20G to 30G

Length: from 10mm to 100mm



**Annex 1 to Certificate n° 166-02-00-DM**

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**PH $\alpha$  $\beta$ XXYY**

Alcoholization needle. PH=  
Needle family field

$\alpha$ = variable field for tip version: Trocar (C) or open (A)

$\beta$ = variable field for holes number (from 3 to 15) – only for C version XX= Gauge

YY= Length [cm]

Diameter: from 18G to 23G

Length: from 50mm to 350mm

**PN $\alpha$  $\beta$  $\chi$  $\delta$ XXYY**

Not repositionable needle for mammary localization. PN=  
Needle family field

$\alpha$ = variable field standard cone type, modified (S), DE type needle (A)

$\beta$ = variable field for hook: standard (*omissis*) o X, Z, K

$\chi$ = variable field for Stiffener: *omissis* (absent), T (present)

$\delta$ = variable field for the positioner: *omissis* (absent), P (present) – except for PNA code XX= Gauge

YY= Length [cm]

Diameter: from 18G to 21G

Length: from 50mm to 200mm

**PR $\alpha$  $\beta$  $\chi$  $\delta$ XXYY**

Repositionable needle for mammary localization. PR=  
Needle family field

$\alpha$ = variable field for material type: standard (*omissis*), MRI material (M)

$\beta$ = variable field for needle type: standard (*omissis*), DE type (A)

$\chi$ = variable field for hook type: *omissis* (single), double (D)

$\delta$ = variable field for Stiffener: *omissis* (absent), T (present) XX= Gauge

YY= Length [cm]

Diameter: from 18G to 21G

Length: from 50mm to 200mm

**STIFF**

Stiffener

Outer diameter 0,60mm- inner 0,40mm

Length: from 50mm to 200mm

**DR $\alpha$ XXYY**

Drainage needle.

DR= Needle family field

$\alpha$ = variable field: standard version (*omissis*), holtec version (H); XX= Gauge

YY= Length [mm]

Diameter: from 8G to 21G

Length: from 30mm to 300mm



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**AV $\alpha\beta$ xyyyS**

Paracentesis / thoracentesis set.

AV= family field

 $\alpha$ = plastic material type: 01 with stopcock; 02 one-way valve. $\beta$ = if the set contains 3 needles of different gauge: "Tzz" with zz= 50mm or 80mm; single Verres needle set: "omissis", Verres needle and catheter set: "L", cannula needle set: "K".

xx= Gauge (only for single needle set).

yy= Verres needle length or 3 needles length (the 3 needles have the same length).

 $\gamma$ = variable field for stylet type: (A) open tip stylet; (B) 2 holes tip stylet; (C) 3 holes tip stylet. S= bag dimension:

"omissis": 2L, "5": 5L, "8": 8L.

Diameter: from 8G to 21G

Length: from 30mm to 300mm

**AV0102**

Drainage set. Diameter: from 8G to 21G. Length: from 30mm to 300mm.

**AV $\alpha\beta$ k $\gamma$ xyyy**

Verres needle.

AV= family field

 $\alpha$ = metallic part version: "A" open tip; "B" 3 holes; "C" 2 holes; "D" 1 hole.  $\beta$ = presence of a catheter: "L" with a catheter; no value if without catheter.

K= "Q" 30° sharpening and stopcock; "no value" 16° sharpening, without stopcock.

 $\chi$ = safety Vise®: "R": with Vise®; no value: without Vise®.  $\gamma$ = no value:

standard, "E": with PTFE ecobright coating. xx= Gauge (only for single needle set).

yy= Nominal length

Diameter: from 8G to 21G

Length: from 30mm to 300mm

**AV $\alpha$ axy1 $\gamma$ Ty2nS**

Paracentesis / thoracentesis set with Verres and hypodermic needles.

Diameter: from 8G to 21G

Length: from 30mm to 300mm

**AV $\alpha\beta$ xx y1 $\gamma$ K nS**

Paracentesis / thoracentesis set with drainage needle.

Diameter: from 8G to 21G

Length: from 30mm to 300mm

**PL**

Automatic reusable device for soft tissue biopsy.

**AEK $\alpha$ X1X1Y1 Y1\_X2 X2Y2 Y2**

Electroneurostimulation needle.

AEK= family field for the double needle

 $\alpha$ = variable field for the tip: T (lancet tip 16°), Q (Quinke tip, lancet 30°), C (Chiba tip), Y (lancet tip 20°), P (pencil point) X1X1= first needle gauge

Y1 Y1= first needle length X2

X2=second needle gauge Y2 Y2=

second needle length

Diameter: from 14G to 30G

Length: from 10mm to 200mm



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**KAεαβXXYYYYμ**

Electroneurostimulation kit.

K= family field Kit

AEαβXXYYYY= AE needle enclosed in the kit

μ= variable field for colour: *omissis* (standard), W (white), Y (yellow), P (pink), G (green)

Diameter: from 14G to 30G

Length: from 10mm to 200mm

**RFαXXYYYYβZZγδε**

Radiofrequency probe introducer needle.

RF: radiofrequency family field

α: variable field for specific customer: *omissis* (MDL line); 0M (customized line)

XX: Gauge

YYY: Nominal needle length

β: variable field for tip geometry: R (straight), C (bent)

ZZ: length of the uncovered tip: *omissis* (uncovered needle), 10 (10mm), 05 (5 mm) or 03 (3 mm)

γ: variable field for junction and tag for customer: *omissis* (absent), A (present for "ATTIVA" machinery), T (present for "ThermaD.A.S." machinery)

δ: variable field for tiptype: *omissis* (only for customer needle, RF0M codes, always blunt tip), B (blunt), S (sharp), P (spoon)

ε: variable field indicating the compatibility probe: *omissis* (MDL); 0 (specific probe)

Diameter: from 11G to 24G

Length: from 30mm to 200mm

**L52203700100, L52203700200, L52203700300, L52203700400**

Junction for radiofrequency probe introducer specific for needle with length from 50 mm to 200 mm.

**PU<sub>n.n1</sub>**

Skin and mucous membranes biopsy. PU=

Family field "biopsy punch"

n.n1= variable field for dimension [mm]

n.n1 value between 1.0 mm and 8.0 mm (1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 7.0, 8.0) mm.

**CU<sub>n.0</sub>**

Skin and mucous membranes biopsy.


CU= Family field "curette"

n.0= variable field for dimension [mm]

n.0 value between 2.0 mm and 7.0 mm.

Milan, 2018-12-20



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