

Notified Body n° 0426



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CERTIFICATE N° 013-05-00-DM
(in compliance with Annex II of the Directive 93/42/EEC)

ITALCERT

certifies the

Full Quality Assurance System
applied for the design, manufacture and final inspection
of "Medical Devices" - MD -

STERYLAB S.r.l.

Via Magenta 77/6 - 20017 RHO (MI) - ITALY

in the headquarters located in

Via Magenta 77/6
20017 RHO (MI) - ITALY

complies with the requirements stated in

Directive 93/42/EEC - Annex II (excluding point 4)

and authorizes the same manufacturer to mark

CE 0426

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

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This certificate must be published only in integral form and accompanied by its Annex 1
This certificate is the English translation of the certificate n° 013-05-00-DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

Annex 1 to Certificate n° 013-05-00-DM

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Surgically Invasive Medical Devices for Transient Use (CLASS IIa)

- Sterile single use instruments, made with stainless steel, for guillotine cutting biopsy on soft tissue:
 - Manual operating, with needles with 7 cm up to 47 cm length and with 14G up to 20G diameter; **BIO-CUT® (catalogue numbers BCT xxyy)**
 - Manual operating to be used with one hand, with needles with 10 cm up to 49 cm length and with 14G up to 18G diameter; **HAND-CUT® (catalogue numbers HCT xxyy)**
 - Automatic operating, with needles with 5 cm up to 47 cm length and with 14G up to 20G diameter; **COLT® (catalogue numbers CLT xxyy)**
 - Semi-automatic operating, with needles with 11 cm up to 47 cm length and with 14G up to 20G diameter; **SPRING-CUT® (catalogue numbers SPG xxyy)**
- Sterile single use instruments made with stainless steel, for aspiration cutting biopsy on soft tissue:
 - with needles with 9 cm up to 20 cm length and with 16G up to 18G diameter; **HISTO-CUT® (catalogue numbers HCI xxyy)**
 - with cytological expulsion valve, with needles with 9 cm to 20 cm length and with 19G up to 22G diameter; **HISTO-CUT® sa (catalogue numbers HCS xxyy)**
 - with modified Menghini type needles with 9 cm up to 20 cm length and 15G up to 22G diameter ; **ATA-CUT® (catalogue numbers ATC xxyy)**
- Sterile single use needles made with stainless steel, for localization and biopsy of mammary lesion:
 - with 21G diameter and lengths from 3 cm to 15 cm, with simple hook wire; **MAMMOREP® NORMAL (catalogue numbers MRN xxyy)**
 - adjustable, with 20G diameter and lengths from 6 cm to 15 cm, with simple adjustable hook wire; **MAMMOREP® J (catalogue numbers MRJ xxyy)**
 - adjustable, with 20G diameter and lengths from 3 cm to 15 cm, with simple stereotaxy adjustable hook wire; **MAMMOREP® XJ (catalogue numbers MRX xxyy)**
 - with 20G diameter and lengths from 3 cm to 15 cm, with double hook wire; **MAMMOREP® ZETA (catalogue numbers MRZ xxyy)**
- Sterile single use Chiba needles for cytological biopsy on soft tissue, with 5 cm up to 35 cm length and with 18G up to 25G diameter; **COMPLETE-CHIBA® (catalogue numbers CCH xxyy)**
- Sterile single use Chiba needles in ECHONOX® stainless steel for cytological biopsy on soft tissue, with 5 cm up to 35 cm length and with 18G up to 25G diameter; **ECOCHIBA® (catalogue numbers ECX xxyy)**
- Sterile single use guiding needle for coaxial biopsy technique on soft tissue to be used with devices Model COLT®, SPRING-CUT® and AUTO-CORE®; **AGC (catalogue numbers AGC xxyy), AGS (catalogue numbers AGS xxyy), AGA (catalogue numbers AGA xxyy).**
- Sterile single use instruments with sample retention trapping device for bone biopsy and/or for bone marrow harvesting, with needles with 9 cm up to 15 cm length and 7G up to 13G diameter; **BEST® (catalogue numbers BST xxyy)**
- Sterile single use instruments for bone marrow aspiration, with needles with 11G up to 15G and lengths from 7 cm to 13 cm; **BEST®-BTT (catalogue numbers BTT xxyy)**
- Sterile single use instruments for bone marrow biopsy/harvesting with needles with 8G and 13G diameter and lengths from 9 cm to 15 cm; **OSTEO-MIELO-CUT® (catalogue numbers OMC x)**
- Sterile single use instruments for bone marrow biopsy, with Safe-Lock® accessory, with needles with 7G and 15G diameter and lengths from 5 cm to 15 cm; **BEST-LISAS® (catalogue numbers BSL xxyy)**
- Sterile single use instruments for bone marrow biopsy, with needles with 7G up to 13G and lengths from 5 cm to 20 cm; **BEN® (catalogue numbers BEN xxyy)**
- Sterile single use instruments for bone marrow aspiration/harvesting **MIELO-CAN® (catalogue numbers MCN01 - MCN02 - MCN22 - MCN03 - MCN04 - MCN05 - MCN022L)**

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- Sterile single use instrument for aspiration cutting biopsy on soft tissue:
 - with needle with 9 cm up to 20 cm length and with 16G up to 18G diameter; **HISTO-TAC® (catalogue numbers HTI xxyy)**
 - with cytological expulsion valve, with needle with 9 cm up to 20 cm length and 19G up to 22G diameter, to be used with the CT; **HISTO-TAC® sa (catalogue numbers HTS xxyy)**
- Sterile single use needles for aspiration cutting biopsy on soft tissue with 6 cm up to 20 cm length and with 16G up to 22G diameter; **TWIN-NEEDLE® (catalogue numbers TWN xxyy)**
- Sterile single use set for corial villi sampling constituted by an external guiding cannula with 18G diameter and 11 cm up to 15 cm length and a cannula with 20G diameter and 17 cm up to 20 cm length; **VCS®.(catalogue numbers VCS xxyy)**
- Sterile single use Westcott type needle for aspiration cutting biopsy on soft tissue with 9 cm up to 20 cm length and with 20G diameter; **WESTCOTT®.(catalogue numbers WST xxyy)**
- Sterile single use instrument made with stainless steel for automatic aspiration cutting biopsy on soft tissue, modified Menghini type, with 6 cm up to 20 cm length and with 16G up to 17G diameter; **AUTO-CORE®.(catalogue numbers ACR xxyy)**
- Sterile single use instrument, with a cannula made with ECHONOX® stainless steel, for automatic aspiration cutting biopsy on soft tissue, to be used with the CT, modified Menghini type, with 7 cm up to 20 cm length and with 18G up to 22G diameter; **AUTO-CORE®.(catalogue numbers ACR xxyy T)**
- Sterile single use needle, made with stainless steel, for guillotine cutting biopsy on soft tissue, to be used with automatic guns FAST GUN, with 7 cm up to 47 cm length and with 14G up to 21G diameter ; **FAST-CUT® (catalogue numbers FSC xxyy)**
- Sterile single use instrument for skin and oral tissues biopsy **DERMO-PUNCH®**, with stainless steel blade with 1 mm up to 8 mm diameter. **(catalogue numbers DMP xx)**
- Sterile single use instruments with sample retention trapping device for bone biopsy with needles with 9 cm up to 15 cm length and 7G up to 13G diameter, with centimetered cannula **BEST® (catalogue numbers BST xxyy C)**
- Sterile single use instruments for bone marrow biopsy, with Safe-Lock® accessory, with needles with 9G and 11G diameter and lengths from 10 cm up to 15 cm; **BEST-LISAS® (catalogue numbers BSL xxyy C)**
- Sterile single use instruments for guillotine cutting biopsy on soft tissue:
 - Manual operating to be used with one hand, with ECHONOX® steel cannula, with needles with 10 cm up to 49 cm length and with 14G up to 18G diameter; **HAND-CUT®(catalogue numbers HCT xxyy +)**.
 - Manual operating to be used with one hand, with ECHONOX® steel cannula and a V-section mandrel with needles with 10 cm up to 49 cm length and with 14G up to 18G diameter; **HAND-CUT® (catalogue numbers HCT xxyy ++)**
 - Automatic operating, with ECHONOX® steel cannula, with needles with 7 cm up to 47 cm length and with 14G up to 20G diameter; **COLT® (catalogue numbers CLT xxyy +)**
 - Automatic operating, with ECHONOX® steel cannula and a V-section mandrel, with needles with 7 cm up to 47 cm length and with 14G up to 18G diameter; **COLT® (catalogue numbers CLT xxyy ++)**
 - Automatic operating, for senology, with stainless steel cannula, with needles with 6 cm up to 10 cm length and with 14G up to 20G diameter **COLT® Short (catalogue numbers CLT xxyy S)**
 - Automatic operating, for senology, with ECHONOX® steel cannula, with needles with 6 cm up to 10 cm length and with 14G up to 20G diameter; **COLT® Short (catalogue numbers CLT xxyy S+)**
 - Automatic operating, for senology, with ECHONOX® steel cannula and a V-section mandrel, with needles with 6 cm up to 10 cm length and with 14G up to 18G diameter; **COLT® Short (catalogue numbers CLT xxyy S++)**
 - Automatic operating, with removable stainless steel cannula, with needles with 11 cm up to 25 cm length and with 14G up to 20G diameter **COLT® DC (catalogue numbers CLT xxyy DC)**

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- Automatic operating, with removable ECHONOX® steel cannula, with needles with 11 cm up to 25 cm length and with 14G up to 20G diameter **COLT® DC (catalogue numbers CLT xxyy DC+)**
- Automatic operating, with removable ECHONOX® steel cannula and a V-section mandrel, with needles with 11 cm up to 25 cm length and with 14G up to 18G diameter **COLT® DC (catalogue numbers CLT xxyy DC++)**
- Automatic operating, to be used with CT, with coaxial needles, with removable stainless steel cannula, with needles with 11 cm up to 25 cm length and with 14G up to 20G diameter **COLT® TC (catalogue numbers CLT xxyy TC)**
- Automatic operating, to be used with CT, with coaxial needles, with removable ECHONOX® steel cannula, with needles with 11 cm up to 25 cm length and with 14G up to 20G diameter; **COLT® TC (catalogue numbers CLT xxyy TC+)**
- Automatic operating, to be used with CT, with coaxial needles, with ECHONOX® steel cannula and a V-section mandrel, with needles with 11 cm up to 25 cm length and with 14G up to 18G diameter **COLT® TC (catalogue numbers CLT xxyy TC++)**
- Semi-automatic operating, with ECHONOX® steel cannula, with needles with 11 cm up to 47 cm length and with 14G up to 20G diameter; **SPRING-CUT® (catalogue numbers SPG xxyy +)**
- Semi-automatic operating, with ECHONOX® steel cannula and a V-section mandrel, with needles with 11 cm up to 47 cm length and with 14G up to 18G diameter **SPRING-CUT® (catalogue numbers SPG xxyy ++)**
- Semi-automatic operating, with removable stainless steel cannula, with needles with 11 cm up to 25 cm length and with 14G up to 20G diameter **SPRING-CUT® (catalogue numbers SPG xxyy DC)**
- Semi-automatic operating, with removable ECHONOX® steel cannula, with needles with 11 cm up to 25 cm length and with 14G up to 20G diameter **SPRING-CUT® (catalogue numbers SPG xxyy DC+)**
- Semi-automatic operating, with ECHONOX® steel cannula and a V-section mandrel, with needles with 11 cm up to 25 cm length and with 14G up to 18G diameter **SPRING-CUT® (catalogue numbers SPG xxyy DC++)**
- Semi-automatic operating, to be used with CT, with coaxial needles, with removable stainless steel cannula, with needles with 11 cm up to 25 cm length and with 14G up to 20G diameter **SPRING-CUT® (catalogue numbers SPG xxyy TC)**
- Semi-automatic operating, to be used with CT, with coaxial needles, with removable ECHONOX® steel cannula, with needles with 11 cm up to 25 cm length and with 14G up to 20G diameter **SPRING-CUT® (catalogue numbers SPG xxyy TC+)**
- Semi-automatic operating, to be used with CT, with coaxial needles, with removable ECHONOX® steel cannula and a V-section mandrel, with needles with 11 cm up to 25 cm length and with 14G up to 18G diameter **SPRING-CUT® (catalogue numbers SPG xxyy TC++)**
- Sterile single use instruments made with ECHONOX® steel for aspiration cutting biopsy on soft tissue:
 - with needles with 9 cm up to 20 cm length and with 16G up to 18G diameter **HISTO-CUT® (catalogue numbers HCl xxyy +)**
 - with cytological expulsion valve, with needles with 9 cm up to 20 cm length and with 19G up to 22G diameter **HISTO-CUT®sa (catalogue numbers HCS xxyy +)**
- Sterile single use needles made with ECHONOX® steel, for localization and biopsy of mammary lesion:
 - with 21G diameter and lengths from 3 cm to 15 cm, with simple hook wire; **MAMMOREP® NORMAL (catalogue numbers MRN xxyy +)**
 - with 20G diameter and lengths from 3 cm to 15 cm, with double hook wire **MAMMOREP® ZETA (catalogue numbers MRZ xxyy +)**
- Sterile single use needle, made with ECHONOX® steel, for guillotine cutting biopsy on soft tissue, to be used with automatic guns FAST GUN, with 7 cm up to 47 cm length and with 14G up to 21G diameter **FAST-CUT® (catalogue numbers FSC xxyy +)**

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- Sterile single use needle, made with ECHONOX® steel, for guillotine cutting biopsy on soft tissue, to be used with automatic guns FAST GUN, with 7 cm up to 47 cm length and with 14G up to 21G diameter **FAST-CUT® (catalogue numbers FSC xxyy ++)**
- Sterile single use needle, made with ECHONOX® steel, and V-section mandrel, for guillotine cutting biopsy on soft tissue, to be used with automatic guns BARD MAGNUM, with 7 cm up to 47 cm length and with 14G up to 21G diameter, **FAST-CUT® (catalogue numbers FSC xxyy B)**
- Sterile single use instruments made with ECHONOX® steel, for automatic aspiration cutting biopsy on soft tissue:
 - with 6 cm up to 30 cm length and with 14G up to 22G diameter; **FULL-OPTY® (catalogue numbers FLP xxyy)**
 - to be used with the CT, with coaxial needle, with 6 cm up to 30 cm length and with 14G up to 22G diameter; **FULL-OPTY® Set Tac (catalogue numbers FLP xxyy T)**
- Sterile single use needle, made with ECHONOX® steel for localization and biopsy of mammary lesion:
 - with 21G diameter and lengths from 3 cm to 15 cm, with adjustable "loop" wire; **MAMMOREP® LOOP (catalogue numbers MLE xxyy)**
 - with 21G diameter and lengths from 3 cm to 15 cm, with stereotaxy adjustable "loop" wire; **MAMMOREP® LOOP (catalogue numbers MLX xxyy)**
- Sterile single use instrument for hematobiopsy (bone + bone marrow biopsy) with needle with 9G up to 11G diameter and 10 cm up to 15 cm length **PARAGON® (catalogue numbers PAG xxyy)**
- Sterile single use instrument for hematobiopsy (bone + bone marrow biopsy) with needle with 13G diameter and 5 cm up to 15 cm length; **PARAGON® (catalogue numbers PAG xxyy)**
- Sterile single use instrument for biopsy on soft tissue, automatic operating, with cannula made with ECHONOX® steel with diameter from 13G up to 21G diameter and length from 6 cm up to 47 cm; **MULTICORE (catalogue numbers MLC xxyy).**
- Sterile single use instrument for biopsy on soft tissue, automatic operating, with cannula made with ECHONOX® steel and mandrel with V section with diameter from 13G up to 18G and length from 6 cm up to 47 cm; **MULTICORE (catalogue numbers MLC xxyy +)**
- Sterile single use instrument for biopsy on soft tissue, automatic operating, with removable cannula made with ECHONOX® steel with diameter from 13G up to 21G and length from 6 cm up to 47 cm; **MULTICORE (catalogue numbers MLC xxyy DC)**
- Sterile single use instrument for biopsy on soft tissue, automatic operating, with removable cannula made with ECHONOX® steel and mandrel with V section with diameter from 13G up to 18G and length from 6 cm up to 47 cm; **MULTICORE (catalogue numbers MLC xxyy DC+)**
- Sterile single use instrument for biopsy on soft tissue, automatic operating, with removable cannula and coaxial needle, with cannula made with ECHONOX® steel for TAC and diameter from 13G up to 21G and length from 6 cm up to 47 cm; **MULTICORE (catalogue numbers MLC xxyy TC)**
- Sterile single use instrument for biopsy on soft tissue, automatic operating, with removable cannula and coaxial needle, with cannula made with ECHONOX® steel for TAC mandrel with V section with diameter from 13G up to 21G and length from 6 cm up to 47 cm; **MULTICORE (catalogue numbers MLC xxyy TC+)**
- Sterile single use guiding needle for coaxial biopsy technique on soft tissue to be used with device model FAST-CUT C **(catalogue numbers AGF xxyy)**
- Sterile single use needle for guillotine cutting biopsy on soft tissue to be used with automatic gun ANGIOTECH PROMAG ULTRA and MAGNUM CR-BARD with diameter from 14G to 21G and length from 8 cm to 30 cm **(catalogue numbers FSC xxyy CA, FSC xxyy CB)**
- Sterile single use curette for skin biopsy with diameter from 2 mm to 7 mm **(catalogue numbers DMP xx C)**



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Surgically Invasive Medical Devices for Transient Use for Magnetic Resonance Imaging (CLASS IIa)

- Sterile single use instruments, made with titanium, for guillotine cutting biopsy on soft tissue:
 - Manual operating, with needles with 7 cm up to 20 cm length and with 14G up to 20G diameter; **BIO-CUT® MR (catalogue numbers BCT xxyy MR)**.
 - Manual operating to be used with one hand, with needles with 7 cm up to 18 cm length and with 14G up to 18G diameter; **HAND-CUT® MR (catalogue numbers HCT xxyy MR)**.
 - Semi-automatic operating, with needles with 7 cm up to 20 cm length and with 14G up to 20G diameter; **SPRING-CUT® MR (catalogue numbers SPG xxyy MR)**.
- Adjustable sterile single use needle, made with titanium, for localization and biopsy of mammary lesion with 20G diameter and lengths from 6 cm up to 15 cm, with adjustable simple hook wire; **MAMMOREP® MR (catalogue numbers MRX xxyy MR)**.
- Sterile single use Chiba needles, made with titanium, for cytological biopsy on soft tissue, with 7 cm up to 25 cm length and with 18G up to 22G diameter; **COMPLETE-CHIBA® MR (catalogue numbers CCH xxyy MR)**
- Sterile single use guiding needle, made with titanium, for coaxial biopsy technique on soft tissue to be used with devices Model COLT, SPRING-CUT and AUTO-CORE; **AGC MR (catalogue numbers AGC xxyy MR)**, **AGS MR (catalogue numbers AGS xxyy MR)**, **AGA MR (catalogue numbers AGA xxyy MR)**.
- Sterile single use needles, made with titanium, for aspiration cutting biopsy on soft tissue with 7 cm up to 29 cm length and with 16G up to 22G diameter; **TWIN-NEEDLE® MR (catalogue numbers TWN xxyy MR)**
- Sterile single use instrument, made with titanium, for automatic aspiration cutting biopsy on soft tissue, modified Menghini type, with 7 cm up to 20 cm length and with 18G up to 22G diameter; **AUTO-CORE® MR (catalogue numbers ACR xxyy MR)**
- Sterile single use instruments made with titanium, for guillotine cutting biopsy on soft tissue:
 - Automatic operating, with 7 cm up to 20 cm length and with 14G up to 20G diameter; **COLT® MR (catalogue numbers CLT xxyy MR)**
 - Automatic operating, with coaxial needle, with removable cannula, with 11 cm up to 25 cm length and with 14G up to 18G diameter; **COLT® MRSET (catalogue numbers CLT xxyy MRSET)**
 - Semi-automatic operating, with coaxial needle, with removable cannula, with 11 cm up to 25 cm length and with 14G up to 18G diameter; **SPRING-CUT® MRSET (catalogue numbers SPG xxyy MRSET)**
- Sterile single use instruments made with titanium, for automatic aspiration cutting biopsy on soft tissue:
 - with coaxial needle, with 6 cm up to 30 cm length and with 14G up to 22G diameter; **FULL-OPTY® MR (catalogue numbers FLP xxyy MR)**
- Sterile single use instrument for biopsy on soft tissue, automatic operating, made with titanium for magnetic resonance imaging with diameter from 14G up 20G and length from 11 cm up to 20 cm; **MULTICORE (catalogue numbers MLC xxyy MR)**
- Sterile single use instrument for biopsy on soft tissue, automatic operating, made with titanium for magnetic resonance imaging with removable cannula and coaxial needle with diameter from 14G up to 18G and length from 11 cm up to 20 cm; **MULTICORE (catalogue numbers MLC xxyy MRSET)**

Active Medical Device intended for removing substances from the body (CLASS IIa)

- Automatic gun to be used with the sterile disposable needle for guillotine cutting biopsy on soft tissue, model FAST CUT; **FAST-GUN® (catalogue number FSG02)**, **FAST-GUN® LIGHT (catalogue number FSG03)**
- Semi-automatic gun to be used with the sterile disposable needle for guillotine cutting biopsy on soft tissue, model BIO CUT; **AUTO-SHOT® (catalogue numbers PSTASH1)**

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Invasive Medical Devices with Respect to Body Orifices for Transient Use (CLASS IIa)

- Single use sets for endometrial biopsy according to the Vabra method:
 - with cannula with 3 mm up to 5 mm diameter and with 220 mm length (**catalogue numbers VBR xx**)
 - with cannula with 3 mm up to 5 mm diameter and with 340 mm length (**catalogue numbers VBR xx L**)
- Single use cannula for intra-uterine aspiration according to the Karman method:
 - with straight flexible cannula with 7 mm up to 12 mm diameter (**catalogue numbers KDF xx**)
 - with angled flexible cannula with 7 mm up to 12 mm diameter (**catalogue numbers KAF xx**)
 - with rigid straight cannula with 7 mm up to 12 mm diameter (**catalogue numbers KDR xx**)
 - with angled rigid cannula with 7 mm up to 12 mm diameter (**catalogue numbers KAR xx**)

Surgically Invasive Medical Devices for Transient Use (CLASS IIb / IIa)

- Sterile single use instruments for liver biopsy following Menghini method constituted by needle with 7 cm up to 20 cm length and with 15G up to 18G diameter, scalpel, triplex sharpening needle and syringe ; **HEPA-CUT® (catalogue numbers HPC xxyy)**
- Sterile single use set for necrotisation through intratumoral injection of ethanol constituted by a plastic tube connected to a needle with 5 cm up to 25 length and 16G up to 25G diameter, versions with open tips **PIA®-A (catalogue numbers PIA xxyyzz)** and closed tips **PIA®-B (catalogue numbers PIB xxyyzz)**
- Sterile single use set for injection of contrast liquid into the galactoforic ducts constituted by a plastic connecting tube of 10 cm up to 60 cm length, connected to a terminal cannula of 27G diameter and length 1 cm and 2 cm; **SGL® (catalogue numbers SGL xxyyz)**
- Sterile single use instrument for creating a pneumoperitoneum through the insufflation of the low pressure inert gas (CO2) with a Verres needle with 14G diameter and with 12 cm and 15 cm length; **VER-FLOW® (catalogue numbers VRF xxyy)**
- Sterile single use set to wash the galactoforic ducts constituted by a plastic connecting tube of 20 cm up to 30 cm length, connected to a terminal cannula of 23G up to 27G diameter and length 1 cm and 2 cm; **MAMMOFLUSH® (catalogue numbers MMF xx)**
- Sterile single use set for necrotisation through intratumoral injection of ethanol constituted by a plastic tube connected to a ECHONOX® stainless steel needle with 5 cm up to 25 length and 16G up to 25G diameter, with open tips needle **PIA®-A (catalogue numbers PAE xxyyzz)** and closed tips needle **PIA®-B (catalogue numbers PBE xxyyzz)**
- Sterile single use set MAMMOFLUSH® with two one-way faucets, a syringe with three rings and a 12 ml syringe, both with an aspiration block **MAMMOFLUSH® (catalogue numbers MMF xx S)**
- Sterile single use needles for liver biopsy following Menghini method with 9 cm up to 15 cm length and with 16G up to 20G diameter; **HEPA-CUT® (catalogue numbers HPC xxyy C)**
- Disposable set for bone cement injection in vertebroplastic percutaneous procedure, with a needle length from 10 cm to 15 cm and size from 11G to 15G (releases "A", "B", "D") and for bone biopsy procedure with "Jamshidi" type needle (release "C"); **VERTOPLAST® (catalogue numbers VRT xxyy A, VRT xxyy B, VRT xxyy C, VRT xxyy D)**
- Sterile single use straight Huber needle for infusion, with little wings and female luer, with 19G up to 22G diameter and 15 cm and 32 cm length; **PORT-JECT® (catalogue numbers PRT xxyy A)**
- Sterile single use angled (90°) Huber needle for infusion, with little wings and female luer, with 19G up to 22G diameter and 15 cm and 32 cm length; **PORT-JECT® (catalogue numbers PRT xxyy B)**
- Set constituted by sterile single use angled Huber needle for infusion, extension, clamp, female luer connector, with 19G up to 22G diameter and 15 cm and 32 cm length; **PORT-JECT® (catalogue numbers PRTxxyy C)**

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- Set constituted by sterile single use angled Huber needle for infusion, extension, Y-infusion point, clamp, female luer connector, with 19G up to 22G diameter and 15 cm and 32 cm length; **PORT-JECT® (catalogue numbers PRT xxyy D)**
- Set constituted by sterile single use angled Huber needle-gripper for infusion, extension, clamp, female luer connector, with 19G up to 22G diameter and 15 cm and 32 cm length; **PORT-JECT® (catalogue numbers PRT xxyy E)**
- Set constituted by sterile single use angled Huber needle-gripper for infusion, extension, Y-infusion point, clamp, female luer connector, with 19G up to 22G diameter and 15 cm and 32 cm length; **PORT-JECT® (catalogue numbers PRT xxyy F)**

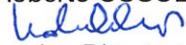
Surgically invasive medical devices intended for transient use and intended specifically for use in direct contact with the central nervous system (CLASS III)

- Sterile single use needles for regional anesthesia with 20G up to 29G diameter and length 5 cm up to 11 cm; **DURA-JECT®.(catalogue numbers DRJ xxyy)**
- Sterile single use needles for regional anesthesia, with insertion needle, with 20G up to 29G diameter and length 5 cm up to 11 cm; **DURA-JECT®.(catalogue numbers DRJ xxyy I)**
- Sterile single use needles for regional anesthesia, with insertion needle, with 18G diameter and length 9 cm up to 15 cm; **DURA-JECT®.(catalogue numbers DRJ xxyy I)**

Surgically Invasive Medical Devices for Transient Use (CLASS IIa)

- Sterile single use instruments for bone marrow biopsy with needles from 9G to 13G diameters and lengths from 5 cm to 15 cm – version DUAL; **BEST-LISAS® DUAL (catalogue numbers BSL xxyy D)**
- Sterile single use instruments for bone marrow aspiration/harvesting for use on the iliac crest: needles with 13G – 14G – 15G diameters and 6 cm – 8 cm – 10 cm lengths **MIELO-CAN® ILIAC (catalogue numbers MCN02I - MCN04I – MCN05I)**

Milan, 2017-06-08

dr. ing. Roberto CUSOLITO

Managing Director