

CERTIFICATE N° 178-01-01-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

BIOMEDICAL S.r.l.

via G.B. Lulli, 43 - 50144 FIRENZE (FI) - ITALY

in the headquarters located in

via G.B. Lulli, 43
50144 FIRENZE (FI) - ITALY

complies with the requirements stated in

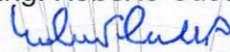
Directive 93/42/EEC - Annex V

and authorizes the same 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
2011-11-03

Renewal date
2016-11-22

Current Emission
2018-02-23

Expire Date
2021-11-02

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Surgically Invasive Medical Devices for Transient Use (Class IIa)

Code	XX	YY(Y)	Z(ZZ)	αα	Description
0Blxxy/zzz-αα	from 14G to 18G	from 05 to 99 mm	from 005 to 300 mm		0BI = disposable needle for sternal or iliac aspiration
0BIPxxy/zzz-αα	from 14G to 18G	from 05 to 99 mm	from 005 to 300 mm		0BIP = pre-assembled disposable needle for sternal or iliac aspiration
0BIExxy/zzz-αα	from 14G to 18G	from 05 to 99 mm	from 005 to 300 mm		0BIE = medullar disposable needle for removal and perfusion
0BILxxy/zzz-αα	from 14G to 25G	from 05 to 99 mm	from 005 to 300 mm		0BIL = disposable needle for iliac aspiration with ergonomic handle
0BILExxy/zzz-αα	from 14G to 25G	from 05 to 99 mm	from 005 to 300 mm		0BILE = disposable needle for iliac aspiration with ergonomic handle for medullar removal
0BLxxy-αα	from 07G to 18G	from 05 to 25 cm	---		0BL = disposable needle for bone – medullar biopsy
0BLExxy-αα	from 07G to 18G	from 05 to 25 cm	---		0BLE = disposable needle for medullar removal with lateral holes
0BWxxy-αα	from 07G to 18G	from 05 to 25 cm	---		0BW = Disposable needle for bone - medullar biopsy (patent SOMATEX)
0BLTxxy-αα	from 07G to 18G	from 05 to 25 cm	---		0BLT = disposable needle for bone – medullar biopsy (Trap System-type)
0PSxxy-αα	from 07G to 18G	from 05 to 25 cm	---		0PS = needle for bone biopsy with inside capturing device. PJ-type handle
0BMxxy-αα	from 11G to 22G	from 05 to 50 cm	---		0BM = disposable needle for soft tissue biopsy with manual action
0BDxxy-αα	from 14G to 22G	from 05 to 50 cm	---		0BD = Disposable guillotine needle for soft tissue biopsy with semiautomatic action

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
0BDSxxyy-αα	from 14G to 22G	from 05 to 50 cm	---		0BDS = disposable guillotine needle for soft tissue biopsy with semiautomatic action (shuttle handle), without removable cannula
0BDPxxyy-αα	from 14G to 22G	from 05 to 50 cm	---		0BDP = disposable guillotine needle for coaxial biopsy
0BDPSxxyy-αα	from 14G to 22G	from 05 to 50 cm	---		0BDPS = disposable guillotine needle for coaxial soft tissue biopsy with semiautomatic action (shuttle handle)
0BDPPxxyy-αα	from 14G to 22G	from 05 to 50 cm	---		0BDPP = disposable guillotine needle for biopsy with semiautomatic action with coaxial introducer
0BExxxy-αα	from 14G to 22G	from 05 to 50 cm	---		0BE = disposable guillotine needle for automatic gun
0BECxxyy-αα	from 14G to 22G	from 05 to 50 cm	---		0BEC = disposable guillotine needle for automatic gun with coaxial introducer
0BExxxy-01	from 14G to 22G	from 05 to 50 cm	---	01 = Promag 2.5 version	0BE = disposable guillotine needle for automatic gun - Promag 2.5 version -
0BECxxyy-01	from 14G to 22G	from 05 to 50 cm	---	01 = Promag 2.5 version	0BEC = disposable guillotine needle for automatic gun - Promag 2.5 version with coaxial introducer
0PGxxyy-αα	from 14G to 22G	from 05 to 50 cm	---		0PG = disposable guillotine needle compatible with Bard Magnum automatic gun
0PGCxxyy-αα	from 14G to 22G	from 05 to 50 cm	---		0PGC = disposable guillotine needle with coaxial introducer compatible with Bard Magnum automatic gun
0BSxxyy-αα	from 14G to 20G	from 10 to 25 cm	---		0BS = automatic disposable gun for soft tissue biopsy (BIOSHOT)
0ITxxyy-αα	from 11G to 23G	from 02 to 50 cm	---		0IT = disposable introducer coaxial needle for introduction of cannula, biopsy devices, hook wires, catheters or other devices, without mandrel and smoothed tip cannula
0BTxxyy-αα	from 11G to 23G	from 02 to 50 cm	---		0BT = disposable introducer coaxial needle for introduction of cannula, biopsy devices, hook wires, catheters or other devices, with trocar mandrel and biopsy tip cannula

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
0BAxxyy-αα	from 14G to 22G	from 05 to 35 cm	--		OBA = disposable set of hepatic biopsy by aspiration as for Menghini
0BCxxyy-αα	from 14G to 25G	from 05 to 30 cm	---		OBC = disposable needle of histological and cytological biopsy by aspiration as for Menghini modified
0BCAxxyy-αα	from 14G to 25G	from 05 to 30 cm	---		0BCA = automatic disposable needle histological and cytological biopsy by aspiration as for Menghini modified
0BCACxxyy-αα	from 14G to 25G	from 05 to 30 cm	---		0BCAC = automatic disposable needle histological and cytological biopsy by aspiration as for Menghini modified with coaxial introducer
0MEMxxyy-αα	from 16G to 26G	from 05 to 30 cm	---		0MEM = Chiba disposable needle for cytological and histological aspiration or insertion, Menchetti version
0MEFxxyy-αα	from 16G to 26G	from 05 to 30 cm	----		0MEF = Disposable needle for cytological and histological biopsy, Franseen style
0MEWxxyy-αα	from 16G to 26G	from 05 to 30 cm	---		0MEW = Wescott disposable needle for cytological and histological biopsy
0ICxxyy-αα	from 18G to 23G	from 05 to 35 cm	---		0IC = disposable needle for alcoholization with closed trocar point
0ILxxyy-αα	from 18G to 23G	from 05 to 35 cm	---		0IL = Open pointed disposable needle for alcoholization
0PBm xxyy-αα	from 14G to 29G	from 05 to 30 cm	---		0PBM = Chiba disposable needle for cytological aspiration and injection, hub LLDU MDL. MRI version
0ME xxyy-αα	from 14G to 29G	from 05 to 30 cm	----		0ME = Chiba disposable needle for cytological aspiration
0ME xxyy-01	from 14G to 29G	from 05 to 30 cm	---	01 = triple sharpening tip	0ME = disposable needle for cytological aspiration triple sharpening tip
0ME xxyy-02	from 14G to 29G	from 05 to 30 cm	---	02 = Quincke tip	0ME = disposable needle for cytological aspiration Quincke tip

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
OMExxyy-03	from 14G to 29G	from 05 to 30 cm	---	03 = Ultra tip	OME = disposable needle for cytological aspiration Ultra tip
OMExxyy-04	from 14G to 29G	from 05 to 30 cm	---	04 = triple sharpening tip Quick Release plug	OME = disposable needle for cytological aspiration triple sharpening tip with Quick Release plug
OMExxyy-05	from 14G to 29G	from 05 to 30 cm	---	05 = Quincke tip with Quick Release plug	OME = disposable needle for cytological aspiration Quincke tip with Quick Release plug
OMExxyy-06	from 14G to 29G	from 05 to 30 cm	----	06 = Ultra tip with Quick Release plug	OME = disposable needle for cytological aspiration Ultra tip with Quick Release plug
OMExxyy-07	from 14G to 29G	from 05 to 30 cm	---	07 = triple sharpening tip with Quick Release plug and extension	OME = disposable needle for cytological aspiration triple sharpening tip with Quick Release plug and extension
OMExxyy-08	from 14G to 29G	from 05 to 30 cm	----	08 = Quincke tip with Quick Release plug and extension	OME = disposable needle for cytological aspiration Quincke tip with Quick Release plug and extension
OMExxyy-09	from 14G to 29G	from 05 to 30 cm	---	09 = Ultra tip with Quick Release plug and extension	OME = disposable needle for cytological aspiration Ultra tip with Quick Release plug and extension
OMEpxxyy-αα	from 16G to 26G	from 050 to 300 mm	----		OMEp = disposable needle for peripheral nerve block under echography – without mandrel – with connecting tube
OMECxxyy-αα	from 16G to 26G	from 05 to 30 cm	---		OMEc = Chiba disposable needle for cytological aspiration, echogenic cannula and tube
OMEBxxyy-αα	from 14G to 26G	from 05 to 30 cm	----		OMEB = disposable needle for brachytherapy

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
0IDxx/Dyy-αα	from 18G to 30G	from 20 to 40 mm	---		0IDxx/D = Set for galactography with straight needle
0IDxx/Cyy-αα	from 18G to 30G	from 20 to 40 mm	---		0IDxx/C = Set for galactography with curved needle
0IDKxx/Cyy-αα	from 18G to 30G	from 20 to 40 mm	---		0IDKxx/C = Kit for galactography with curved needle, 6 dilators and 1ml syringe
0IDKxx/Dyy-αα	from 18G to 30G	from 20 to 40 mm	---		0IDKxx/C = Kit for galactography with straight needle, 6 dilators and 1ml syringe
0IMxxyy-αα	from 14G to 25G	from 05 to 35 cm	---		0IM = disposable needle for mammary localization
0IMXxxyy-αα	from 14G to 25G	from 05 to 35 cm	---		0IMX = disposable needle for mammary localization with double hook
0PNAxxyy-αα	from 14G to 25G	from 05 to 35 cm	---		0PNA = disposable needle for mammary localization, not repositionable; BCA-type handle
0PRxxyy-αα	from 14G to 25G	from 05 to 35 cm	---		0PR = repositionable disposable needle for mammary localization; normal handle
0PRDxxyy-αα	from 14G to 25G	from 05 to 35 cm	---		0PRD = repositionable disposable needle for mammary localization; normal handle with double anchor
0PRAxxyy-αα	from 14G to 25G	from 05 to 35 cm	---		0PRA = repositionable disposable needle for mammary localization; BCA-type handle
0PRADxxyy-αα	from 14G to 25G	from 05 to 35 cm	---		0PRAD = repositionable disposable needle for mammary localization; BCA-type handle with double anchor
0AETxxyyy-αα	from 18G to 30G	from 001 to 200 mm	---		0AET = disposable needle with triple tip for ENS electro stimulation
0AETxxyyy-01	from 18G to 30G	from 001 to 200 mm	---	01 = sharpening 30°	0AET = disposable needle with triple tip for ENS electro stimulation

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
0AEQxxyyy-αα	from 18G to 30G	from 001 to 200 mm	---		0AEQ = disposable needle with Quincke tip for ENS electro stimulation
0AECxxyyy-αα	from 18G to 30G	from 001 to 200 mm	---		0AEC = disposable needle with Chiba tip for ENS electro stimulation
0AEYxxyyy-αα	from 18G to 30G	from 001 to 200 mm	---		0AEY = disposable needle with Thuoy tip for ENS electro stimulation
0AEPxxyyy-αα	from 18G to 30G	from 001 to 200 mm	---		0AEP = disposable needle with pencil point tip and lateral hole for ENS electro stimulation
0AV01xxyyA	from 12G to 20G	from 05 to 25 cm	A = open tip		0AV01xxyyA = set for thoracentesis / paracentesis with tap and Verres needle, with open tip mandrel
0AV01xxyyB	from 12G to 20G	from 05 to 25 cm	B = 2 holes		0AV01xxyyB = set for thoracentesis / paracentesis with tap and Verres needle, with 2 holes mandrel
0AV01xxyyC	from 12G to 20G	from 05 to 25 cm	C = 3 pits		0AV01xxyyC = set for thoracentesis / paracentesis with tap and Verres needle, with 3 pits mandrel
0AV0103yy	03	from 05 to 25 cm	---		0AV0103yy = set for thoracentesis / paracentesis with tap and 3 needles
0AV02xxyyA	from 12G to 20G	from 05 to 25 cm	A = open tip		0AV02xxyyA = set for thoracentesis / paracentesis with valve and one Verres needle with open tip mandrel
0AV02xxyyB	from 12G to 20G	from 05 to 25 cm	B = 2 holes		0AV02xxyyB = set for thoracentesis / paracentesis with valve and one Verres needle with 2 holes mandrel
0AV02xxyyC	from 12G to 20G	from 05 to 25 cm	C = 3 pits		0AV02xxyyC = set for thoracentesis / paracentesis with valve and one Verres needle with 3 pits mandrel
0AV0203yy	03	from 05 to 25 cm	---		0AV0203yy = set for thoracentesis / paracentesis with valve and 3 needles
0AV03xxyyy	from 08 to 21G	from 030 to 300 mm	---		0AV03xxyyy = set for thoracentesis / paracentesis for removal of ascites and drainage needle

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
0AV0102	---	---	---		0AV0102 = set for drainage with 2 funnel needles, tap and tube 4,1 x 3 mm.
0AVAxxyy	from 12G to 20G	from 05 to 25 cm	---		0AVAxxyy = Verres needle with normal slim joint, open point, 16° sharpen, without tap
0AVBxxyy	from 12G to 20G	from 05 to 25 cm	---		0AVBxxyy = Verres needle with normal slim joint, 2 holes, 16° sharpen, without tap
0AVCxxyy	from 12G to 20G	from 05 to 25 cm	---		0AVCxxyy = Verres needle with normal slim joint, 3 pits, 16° sharpen without tap
0AVDxxyy	from 12G to 20G	from 05 to 25 cm	---		0AVDxxyy = Verres needle with normal slim joint, 1 hole, 16° sharpen without tap
0AVAQxxyy	from 12G to 20G	from 05 to 25 cm	---		0AVAQxxyy = Verres needle with normal slim joint, open tip, 30° sharpen and tap
0AVBQxxyy	from 12G to 20G	from 05 to 25 cm	---		0AVBQxxyy = Verres needle with normal slim joint, 2 holes, 30° sharpen and tap
0AVCQxxyy	from 12G to 20G	from 05 to 25 cm	---		0AVCQxxyy = Verres needle with normal slim joint, 3 pits, 30° sharpen and tap
0AVDQxxyy	from 12G to 20G	from 05 to 25 cm	---		0AVDQxxyy = Verres needle with normal slim joint, 1 hole, 30° sharpen and tap
0AVAxxyy-02	from 12G to 20G	from 05 to 25 cm	---	02 = PTFE cover	0AVAxxyy-02 = Verres needle with normal slim joint, open tip, 16° sharpen without tap and PTFE cover
0AVBxxyy-02	from 12G to 20G	from 05 to 25 cm	---	02 = PTFE cover	0AVBxxyy-02 = Verres needle with normal slim joint, 2 holes, 16° sharpen without tap and PTFE cover
0AVCxxyy-02	from 12G to 20G	from 05 to 25 cm	---	02 = PTFE cover	0AVCxxyy-02 = Verres needle with normal slim joint, 3 pits, 16° sharpen without tap and PTFE cover
0AVDxxyy-02	from 12G to 20G	from 05 to 25 cm	---	02 = PTFE cover	0AVDxxyy-02 = Verres needle with normal slim joint, 1 hole, 16° sharpen without tap and PTFE cover

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
0AVAQxxyy-02	from 12G to 20G	from 05 to 25 cm	---	02 = PTFE cover	0AVAQxxyy-02 = Verres needle with normal slim joint, open tip, 30° sharpen, tap and PTFE cover
0AVBQxxyy-02	from 12G to 20G	from 05 to 25 cm	---	02 = PTFE cover	0AVBQxxyy-02 = Verres needle with normal slim joint, 2 holes, 30° sharpen, tap and PTFE cover
0AVCQxxyy-02	from 12G to 20G	from 05 to 25 cm	---	02 = PTFE cover	0AVCQxxyy-02 = Verres needle with normal slim joint, 3 pits, 30° sharpen, tap and PTFE cover
0AVDQxxyy-02	from 12G to 20G	from 05 to 25 cm	---	02 = PTFE cover	0AVDQxxyy-02 = Verres needle with normal slim joint, 1 hole, 30° sharpen, tap and PTFE cover
0AVAxxyy-01	from 12G to 20G	from 05 to 25 cm	---	01 = normal slim joint	0AVAxxyy-01 = Verres needle with normal slim joint, open tip, 16° sharpen without tap
0AVBxxyy-01	from 12G to 20G	from 05 to 25 cm	---	01 = normal slim joint	0AVBxxyy-01 = Verres needle with normal slim joint, 2 holes, 16° sharpen without tap
0AVCxxyy-01	from 12G to 20G	from 05 to 25 cm	---	01 = normal slim joint	0AVCxxyy-01 = Verres needle with normal slim joint, 3 pits, 16° sharpen without tap
0AVDxxyy-01	from 12G to 20G	from 05 to 25 cm	---	01 = normal slim joint	0AVDxxyy-01 = Verres needle with normal slim joint, 1 hole, 16° sharpen without tap
0AVAQxxyy-01	from 12G to 20G	from 05 to 25 cm	---	01 = normal slim joint	0AVAQxxyy-01 = Verres needle with normal slim joint, open tip, 30° sharpen and tap
0AVBQxxyy-01	from 12G to 20G	from 05 to 25 cm	---	01 = normal slim joint	0AVBQxxyy-01 = Verres needle with normal slim joint, 2 holes, 30° sharpen and tap
0AVCQxxyy-01	from 12G to 20G	from 05 to 25 cm	---	01 = normal slim joint	0AVCQxxyy-01 = Verres needle with normal slim joint, 3 pits, 30° sharpen and tap
0AVDQxxyy-01	from 12G to 20G	from 05 to 25 cm	---	01 = normal slim joint	0AVDQxxyy-01 = Verres needle with normal slim joint, 1 hole, 30° sharpen and tap
0AVAxxyy-03	from 12G to 20G	from 05 to 25 cm	---	03 = normal slim joint and PTFE cover	0AVAxxyy-03 = Verres needle with normal slim joint, open tip, 16° sharpen without tap and PTFE cover

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
0AVBxxyy-03	from 12G to 20G	from 05 to 25 cm	---	03 = normal slim joint and PTFE cover	0AVBxxyy-03 = Verres needle with normal slim joint, 2 holes, 16° sharpen without tap and PTFE cover
0AVCxxyy-03	from 12G to 20G	from 05 to 25 cm	---	03 = normal slim joint and PTFE cover	0AVCxxyy-03 = Verres needle with normal slim joint, 3 pits, 16° sharpen without tap and PTFE cover
0AVDxxyy-03	from 12G to 20G	from 05 to 25 cm	---	03 = normal slim joint and PTFE cover	0AVDxxyy-03 = Verres needle with normal slim joint, 1 hole, 16° sharpen with tap and PTFE cover
0AVAQxxyy-03	from 12G to 20G	from 05 to 25 cm	----	03 = normal slim joint and PTFE cover	0AVAQxxyy-03 = Verres needle with normal slim joint, open tip, 30° sharpen with tap and PTFE cover
0AVBQxxyy-03	from 12G to 20G	from 05 to 25 cm	----	03 = normal slim joint and PTFE cover	0AVBQxxyy-03 = Verres needle with normal slim joint, 2 holes, 30° sharpen with tap and PTFE cover
0AVCQxxyy-03	from 12G to 20G	from 05 to 25 cm	---	03 = normal slim joint and PTFE cover	0AVCQxxyy-03 = Verres needle with normal slim joint, 3 pits, 30° sharpen with tap and PTFE cover
AVDQxxyy-03	from 12G to 20G	from 05 to 25 cm	---	03 = short slim joint and PTFE cover	0AVDQxxyy-03 = Verres needle with short slim joint, 1 hole, 30° sharpen, with tap and PTFE cover
0DRxxyyy	from 08 to 21G	from 030 to 300 mm	----		0DRxxyyy = disposable needle for removal of ascites with mandrel, tube, triple tip, blunt with holes, LDU, PC, TMQ. Package with 50 units
0DRxxyyy-01	from 08 to 21G	from 030 to 300 mm	---	01 = Package with 50 units	0DRxxyyy-01 = disposable needle for removal of ascites with mandrel, tube, triple tip, blunt with holes, LDU, PC, TMQ. Package with 50 units

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Code	XX	YY(Y)	Z(ZZ)	αα	Description
OBLTxyyy-02	from 7 G to 18 G	from 50 mm to 250 mm	-		Disposable needle for bone - medullar biopsy (type Trap System), version with diamond tip
0BDSExyyy-αα	from 11G to 22G	from 50 mm to 500 mm			disposable guillotine needle for soft tissue biopsy with semiautomatic action (shuttle handle), without removable cannula, echogenic version with PTFE
0PGExxyy-αα	from 14G to 22 G	from 50 mm to 500 mm			disposable guillotine needle compatible with Bard Magnum automatic gun, echogenic version with PTFE
0BSExyyy-αα	from 14G to 20G	from 100 mm to 250 mm			automatic disposable gun for soft tissue biopsy (BIOSHOT), echogenic version with PTFE
0ITExyyy-αα	from 11G to 23G	from 20 mm to 500 mm			disposable introducer coaxial needle for introduction of cannula, biopsy devices, hook wires, catheters or other devices, without mandrel and smoothed tip cannula, echogenic version with PTFE
0BTxyyy-αα	from 11G to 23G	from 20 mm to 500 mm			disposable introducer coaxial needle for introduction of cannula, biopsy devices, hook wires, catheters or other devices, with trocar mandrel and biopsy tip cannula

Milan, 2018-02-23

dr. ing. Roberto Cusolito


Managing Director