

## Conformity declaration

The undersigned company BIOMEDICAL S.r.l., declares, on its own responsibility, that the following disposable sterile medical devices produced and supplied by the company itself:

- are in accordance to the essential requirements of Annex I of the European Directive 93/42/EEC and subsequent amendments and additions.
- are classified as surgical invasive medical device for transient use (class IIa) in accordance to the rule 6 , annex IX of Directive 93/42/EEC and subsequent amendments and additions.
- are manufactured in strict accordance with Italian sanitary laws and with European Directive 93/42/EEC and subsequent amendments and additions - Annex V and Annex VII, UNI EN ISO 9001-2008 + UNI ISO 13485-2012 , using medical/pharmaceutical grade materials.

This conformity declaration is related to the certificate number 178-01-01-DM and to the codes listed below.

Firenze, 24/02/2018

BIOMEDICAL S.r.l.  
Legal representative

Paola Giunti  


CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
0Blxxyy/zzz- αα	from 14G to 18G	from 05 to 99 mm	from 005 to 300 mm	---	0BI = disposable needle for sternal or iliac aspiration
0BIPxxyy/zzz- αα	from 14G to 18G	from 05 to 99 mm	from 005 to 300 mm	---	0BIP = pre-assembled disposable needle for iliac or sternal aspiration
0BIExxyy/zzz- αα	from 14G to 18G	from 05 to 99 mm	from 005 to 300 mm	---	0BIE = medullar disposable needle for removal and perfusion
0BILxxyy/zzz- αα	from 14G a to 25G	from 05 to 99 mm	from 005 to 300 mm	---	0BIL = disposable needle for iliac aspiration with ergonomic handle
0BILExxyy/zz z-αα	from 14G a to 25G	from 05 to 99 mm	from 005 to 300 mm	---	0BILE = disposable needle for iliac aspiration with ergonomic handle for medullar removal
0BLxxyy-αα	from 07G to 18G	from 05 to 25 cm	---	---	0BL = disposable needle for bone-medullar biopsy
0BLExxyy-αα	from 07G to 18G	from 05 to 25 cm	---	---	0BLE = disposable needle for medullar removal with lateral holes
0BWxxyy-αα	from 07G to 18G	from 05 to 25 cm	---	---	0BW = disposable needle for bone-medullar biopsy (patent SOMATEX)
0BLTxxyy-αα	from 07G to 18G	from 05 to 25 cm	---	---	0BLT = disposable needle for bone-medullar biopsy (Trap System-type)
0BLTxxyy-02	from 07G to 18G	from 05 to 25 cm	---	02 = diamond shaped tip	0BLT = disposable needle for bone-medullar biopsy (Trap System-type)
0PSxxyy-αα	from 07G to 18G	from 05 to 25 cm	---	---	0PS = needle for bone biopsy with inside capturing device. PJ- type handle

CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
0BMxxyy-αα	from 11G to 22G	from 05 to 50 cm	---	---	0BM = disposable needle for soft tissue biopsy with manual action
0BDxxyy-αα	from 14G to 22G	from 05 to 50 cm	---	---	0BD = disposable needle for soft tissue biopsy with semiautomatic action
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
0BDSExxyy- αα	from 14G to 22G	from 05 to 50 cm	---	---	0BDSE = disposable guillotine needle for soft tissue biopsy with semiautomatic action (shuttle handle), without removable cannula, echogenic version (PTFE covered)
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
0BExxyy-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
0BExxyy-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

CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
0PGExxyy-αα	from 14G to 22G	from 05 to 50 cm	---	---	0PGE = disposable guillotine needle compatible with Bard Magnum automatic gun, echogenic version (PTFE covered)
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)
0BSExxyy-αα	from 14G to 20G	from 10 to 25 cm	---	---	0BSE = automatic disposable gun for soft tissue biopsy (BIOSHOT), echogenic version (PTFE covered)
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
0ITExxyy-αα	from 11G to 23G	from 02 to 50 cm	---	---	0ITE = disposable introducer coaxial needle for introduction of cannula, biopsy devices, hook wires, catheters or other devices, without mandrel and smoothed tip cannula, echogenic version (PTFE covered)
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
0BAxxyy-αα	from 14G to 22G	from 05 to 35 cm	---	---	0BA = disposable set of hepatic biopsy by aspiration as for Menghini
0BCxxyy-αα	from 14G to 25G	from 05 to 30 cm	---	---	0BC = 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 of 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 of histological and cytological biopsy by aspiration as for Menghini modified with coaxial introducer

CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
0MEMxxyy- αα	from 16G to 26G	from 05 to 30 cm	---	---	0MEM = Chiba disposable needle histological and cytological 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
0PBMxxyy-αα	from 14G to 29G	from 05 to 30 cm	---	---	0PBM = Chiba disposable needle for cytological aspiration and injection, hub LLDU MDL. MRI version
0MExxyy-αα	from 14G to 29G	from 05 to 30 cm	---	---	0ME = Chiba disposable needle for cytological aspiration
0MExxyy-01	from 14G to 29G	from 05 to 30 cm	---	01 = Triple sharpening tip	0ME = Chiba disposable needle for cytological aspiration Triple sharpening tip
0MExxyy-02	from 14G to 29G	from 05 to 30 cm	---	02 = Quincke tip	0ME = Chiba disposable needle for cytological aspiration Quincke tip
0MExxyy-03	from 14G to 29G	from 05 to 30 cm	---	03 = Ultra tip	0ME = Chiba disposable needle for cytological aspiration Ultra tip
0MExxyy-04	from 14G to 29G	from 05 to 30 cm	---	04 = Triple sharpening tip and Quick Release plug	0ME = Chiba disposable needle for cytological aspiration Triple sharpening tip and Quick Release plug
0MExxyy-05	from 14G to 29G	from 05 to 30 cm	---	05 = Quincke tip and Quick Release plug	0ME = Chiba disposable needle for cytological aspiration Quincke tip and Quick Release plug
0MExxyy-06	from 14G to 29G	from 05 to 30 cm	---	06 = Ultra tip and Quick Release plug	0ME = Chiba disposable needle for cytological aspiration with Ultra tip and Quick Release plug

CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
OMExxxy-07	from 14G to 29G	from 05 to 30 cm	---	07 = Triple sharpening tip, Quick Release plug and extension	OME = Chiba disposable needle for cytological aspiration Triple sharpening tip Quick Release plug and extension
OMExxxy-08	from 14G to 29G	from 05 to 30 cm	---	08 = punta Quincke, Quick Release plug and extension	OME = Chiba disposable needle for cytological aspiration Quincke tip Quick Release plug and extension
OMExxxy-09	from 14G to 29G	from 05 to 30 cm	---	09 = Ultra tip, Quick Release plug and extension	OME = Chiba disposable needle for cytological aspiration Ultra tip Quick Release plug and extension
OMEpxxyy- αα	from 16G to 26G	from 050 to 300 mm	---	---	OMEp = disposable needle with peripheral nerve block under echography – without mandrel – with connecting tube
OMECxxxy-αα	from 16G to 26G	from 05 to 30 cm	---	---	OMEC = Chiba disposable needle for cytological aspiration, echogenic cannula and tube
OMEBxxxy-αα	from 14G to 26G	from 05 to 30 cm	---	---	OMEB = disposable needle for brachytherapy
OIDxx/Dyy-αα	from 18G to 30G	from 20 to 40 mm	---	---	OIDxx/D = set for galactography with straight needle
OIDxx/Cyy-αα	from 18G to 30G	from 20 to 40 mm	---	---	OIDxx/C = set for galactography with curved needle
OIDKxx/Cyy- αα	from 18G a 30G	from 20 a 40 mm	---	---	OIDKxx/C = set for galactography with curved needle, 6 dilators and 1ml syringe
OIDKxx/Dyy- αα	from 18G to 30G	from 20 to 40 mm	---	---	OIDKxx/D = set for galactography with straight needle, 6 dilators and 1ml syringe
OIMxxxy-αα	from 14G to 25G	from 05 to 35 cm	---	---	OIM = disposable needle for mammary localization
OIMXxxxy-αα	from 14G to 25G	from 05 to 35 cm	---	---	OIMX = disposable needle for mammary localization with double hook

CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
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 = disposable needle for mammary localization; normal handle
0PRDxxyy-αα	from 14G to 25G	from 05 to 35 cm	---	---	0PRD = 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 = 30° angle tip	0AET = disposable needle with triple tip for ENS electro stimulation
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

CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
0AV01xxyyB	from 12G to 20G	from 05 to 25 cm	B = 2 holes	---	0AV01xxyyB = set for thoracentesis/paracentesis with tap and Verres needle, with two 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 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 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 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
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



CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
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
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

CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
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, open tip, 30° sharpen, tap and PTFE cover
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
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

CODE	RANGE XX	RANGE YY(Y)	RANGE Z(ZZ)	αα	DESCRIPTION
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 without 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 without 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 without 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 without tap and PTFE cover
0AVDQxxyy- 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 without tap and PTFE cover
0DRxxxx	from 08 to 21G	from 030 to 300 mm	---	---	0DRxxxx = disposable needle for removal of ascites with mandrel, tube, triple tip, blunt with holes, LDU, PC, TMQ. Package with 20 units
0DRxxxx-01	from 08 to 21G	from 030 to 300 mm	---	01 = Package with 50 units	0DRxxxx-01 = disposable needle for removal of ascites with mandrel, tube, triple tip, blunt with holes, LDU, PC, TMQ. Package with 50 units