



M.V. S.r.l.
Via F.lli Cervi 7 – 46023 – Gonzaga (MN) – ITALY
info@mvsrl.it
www.mvsrl.it
Tel: +39 0376 536 995
VAT ID: IT 01913020200

OGGETTO: DECLARATION OF CONFORMITY

The company M.V. Srl with legal site in via F.lli Cervi, 7 - 46023 Gonzaga (MN), Italy, and operational site in via Don G. Dossetti, 5/7 – 46023 Gonzaga (MN), Italy,

declares that

the following disposable medical devices

CODE	DESCRIPTION
MDHN001	NEEDLE FREE DHN SET
MDHN2704C	DHN SET WITH 27G X 4 MM NEEDLE
MDHN3006C	DHN SET WITH 30G X 6 MM NEEDLE
MDHN3012C	DHN SET WITH 30G X 12 MM NEEDLE
MSIT001	SKIN INJECTION THERAPY DEVICE 31G X 2,5 MM 19 MM
MSIT001B	SKIN INJECTION THERAPY DEVICE 31G X 2,5 MM 19 MM
MSIT003	SKIN INJECTION THERAPY DEVICE 31G X 2,5 MM 16 MM
MLP025	ELETTROLIPOLYSIS 25 MM NEEDLE
MLP050	ELETTROLIPOLYSIS 50 MM NEEDLE
MLP075	ELETTROLIPOLYSIS 75 MM NEEDLE
MLP100	ELETTROLIPOLYSIS 100 MM NEEDLE
MLP125	ELETTROLIPOLYSIS 125 MM NEEDLE
MLP150	ELETTROLIPOLYSIS 150 MM NEEDLE
MLP050B	ELETTROLIPOLYSIS 50 MM NEEDLE
MLP075B	ELETTROLIPOLYSIS 75 MM NEEDLE
MLP100B	ELETTROLIPOLYSIS 100 MM NEEDLE
MLP125B	ELETTROLIPOLYSIS 125 MM NEEDLE
MLP150B	ELETTROLIPOLYSIS 150 MM NEEDLE
MRCA275	CIRCULAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 5 FITTINGS WITH 27G NEEDLE
MRCA305	CIRCULAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 5 FITTINGS WITH 30G NEEDLE
MRLA303	LINEAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 3 FITTINGS WITH 30G NEEDLE
MRLA273	LINEAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 3 FITTINGS WITH 27G NEEDLE
MRLA275	LINEAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 5 FITTINGS WITH 27G NEEDLE
MRLA305	LINEAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 5 FITTINGS WITH 30G NEEDLE
MRLA315	LINEAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 5 FITTINGS WITH 31G NEEDLE
MRC003	CIRCULAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 3 FITTINGS WITHOUT NEEDLES
MRC005	CIRCULAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 5 FITTINGS WITHOUT NEEDLES



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CODE	DESCRIPTION
MRC007	CIRCULAR MESOTHERAPY MULTI-INJECTOR FITTING WITH 7 FITTINGS WITHOUT NEEDLES
MRL003	LINEARMESOTHERAPY MULTI-INJECTOR FITTING WITH 3 FITTINGS WITHOUT NEEDLES
MRL005	LINEARMESOTHERAPY MULTI-INJECTOR FITTING WITH 5 FITTINGS WITHOUT NEEDLES
MILT22090	INTRALIPOTHERAPY NEEDLE 22G X 90 MM
MILT24100	INTRALIPOTHERAPY NEEDLE 24G X 100 MM
M03SBK	BONT KIT™ SET WITH SYRINGE, WITHDRAWAL NEEDLE AND INTRADERMAL NEEDLE
M0127G025	MESOTHERAPY NEEDLE 27G 2.5 MM (REDUCED)
M0127G025R	MESOTHERAPY NEEDLE 27G 2.5 MM (TO BE REDUCED)
M0130G025	MESOTHERAPY NEEDLE 30G 2.5 MM (REDUCED)
M0130G025R	MESOTHERAPY NEEDLE 30G 2.5 MM (TO BE REDUCED)
M0131G025	MESOTHERAPY NEEDLE 31G 2.5 MM (REDUCED)
M0131G025R	MESOTHERAPY NEEDLE 31G 2.5 MM (TO BE REDUCED)
M0132G025	MESOTHERAPY NEEDLE 32G 2.5 MM (REDUCED)
M0132G025R	MESOTHERAPY NEEDLE 32G 2.5 MM (TO BE REDUCED)
M0133G025	MESOTHERAPY NEEDLE 33G 2.5MM (REDUCED)
M0133G025R	MESOTHERAPY NEEDLE 33G 2.5MM (TO BE REDUCED)
M0127G04	MESOTHERAPY NEEDLE 27G 4 MM
M0127G06	MESOTHERAPY NEEDLE 27G 6 MM
M0127G12	MESOTHERAPY NEEDLE 27G 12 MM
M0127G25	MESOTHERAPY NEEDLE 27G 25 MM
M0127G40	MESOTHERAPY NEEDLE 27G 40 MM
M0130G04	MESOTHERAPY NEEDLE 30G 4 MM
M0130G06	MESOTHERAPY NEEDLE 30G 6 MM
M0130G08	MESOTHERAPY NEEDLE 30G 8 MM
M0130G12	MESOTHERAPY NEEDLE 30G 12 MM
M0130G25	MESOTHERAPY NEEDLE 30G 25 MM
M0130G40	MESOTHERAPY NEEDLE 30G 40 MM
M0131G04	MESOTHERAPY NEEDLE 31G 4 MM
M0131G06	MESOTHERAPY NEEDLE 31G 6 MM
M0131G12	MESOTHERAPY NEEDLE 31G 12 MM
M0131G25	MESOTHERAPY NEEDLE 31G 25 MM
M0132G04	MESOTHERAPY NEEDLE 32G 4 MM
M0132G06	MESOTHERAPY NEEDLE 32G 6 MM
M0132G12	MESOTHERAPY NEEDLE 32G 12 MM
M0133G04	MESOTHERAPY NEEDLE 33G 4 MM
M0133G12	MESOTHERAPY NEEDLE 33G 12 MM



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CODE	DESCRIPTION
M0127G12T	MESOTHERAPY NEEDLE 27G 12 MM - THIN
M0130G12 T	MESOTHERAPY NEEDLE 30G 12 MM - THIN
M0222G50	INTRADERMIC NEEDLE 22G x 50 mm + INTRODUCER NEEDLE 21G x 25 mm
M0222G70	INTRADERMIC NEEDLE 22G x 70 mm + INTRODUCER NEEDLE 21G x 25 mm
M0225G40	INTRADERMIC NEEDLE 25G x 40 mm + INTRODUCER NEEDLE 23G x 25 mm
M0225G50	INTRADERMIC NEEDLE 25G x 50 mm + INTRODUCER NEEDLE 23G x 25 mm
M0227G40	INTRADERMIC NEEDLE 27G x 40 mm + INTRODUCER NEEDLE 26G x 13 mm
M0230G30	INTRADERMIC NEEDLE 30G x 30 mm + INTRODUCER NEEDLE 27G x 13 mm
M0222G50S	INTRADERMIC NEEDLE 22G x 50 mm + INTRODUCER NEEDLE 21G x 25 mm
M0222G70S	INTRADERMIC NEEDLE 22G x 70 mm + INTRODUCER NEEDLE 21G x 25 mm
M0225G40S	INTRADERMIC NEEDLE 25G x 40 mm + INTRODUCER NEEDLE 23G x 25 mm
M0225G50S	INTRADERMIC NEEDLE 25G x 50 mm + INTRODUCER NEEDLE 23G x 25 mm
M0227G40S	INTRADERMIC NEEDLE 27G x 40 mm + INTRODUCER NEEDLE 26G x 13 mm
M0230G30S	INTRADERMIC NEEDLE 30G x 30 mm + INTRODUCER NEEDLE 27G x 13 mm

conform to the provisions of the current Directive 93/42/CEE, concerning Medical Devices and therefore bears the CE mark of conformity on its labeling in combination with the Notified Body identification number 0373 of Italian Istituto Superiore di Sanità, Rome, Italy.

Conformity to the applicable Essential Requirements for safety and performance per current Directive 93/42/CEE, Annex I: “Essential Requirements” has been proved, so it offers the benefits granted and it is guaranteed the absence of damage to health and safety of people, provided that the product is used according to the intended purpose.

The device classification (**class IIa, sterile**) has been determined per current Directive 93/42/CEE, Annex IX: “Classification criteria”.

MV’s Quality Management System fulfils the Quality Management System requirements described in the current Directive 93/42/CEE and ISO 13485, as evidenced by the **UNI EN ISO 13485:2021** Certificate No. **0423.2019**. The specified medical device falls within the scope of MV’s Quality Management System as indicated in the certificate.

This declaration of Conformity is valid until **May 26, 2028**,

CE Approval of Quality Assurance System for Production and/or Sterilization n. **QPZ-1916-19**.

M.V. Srl commits to maintain all the production documentation for at least 10 years from manufacturing date.

Gonzaga, 28/05/2024

M.V. S.R.L.

Pag. 3 / 3



M.V. S.r.l.
Cap. Sociale: € 93.600
Sede Legale: Via F.lli Cervi 7,
46023 Gonzaga (MN)
Sede Operativa: Via Don G. Dossetti 5/7,
46023 Gonzaga (MN)
P. IVA: IT 01913020200

