

MEDOJECT® Hypodermic needles



According to EN, ISO standards | Quality management certified according to EN ISO 13485:2016 | CE marked

- ✓ precision lancet point grinding, silicone treated for smooth penetration
- ✓ colored coded transparent hub for flow visual control
- ✓ included all metric and gauge measurements on all packages
- ✓ mainly thin wall tube material
- ✓ made of polypropylene hub and stainless steel tube
- ✓ pyrogen-free, latex-free, DEHP-free, PVC-free, non-toxic
- ✓ 100 pcs per box, 4000 pcs per case sterile, individually blister packed

Size metric	Size G/"	Color code	Item Code
0,30 x 12 mm	30 G x 1/2"	light yellow	CH30012
0,40 x 12 mm	27 G x 1/2"	grey	CH27012
0,40 x 20 mm	27 G x 4/5"	grey	CH27045
0,40 x 20 mm	27 G x 3/4"	grey	CH27034
0,40 x 40 mm	27 G x 1 1/2"	grey	CH27112

MEDOJECT® Hypodermic needles

Size metric	Size G/"	Color code	Item Code
0,45 x 12 mm	26 G x 1/2"	brown	CH26012
0,45 x 16 mm	26 G x 5/8"	brown	CH26058
0,45 x 25 mm	26 G x 1"	brown	CH26100
0,50 x 16 mm	25 G x 5/8"	orange	CH25058
0,50 x 20 mm	25 G x 4/5"	orange	CH25045
0,50 x 25 mm	25 G x 1"	orange	CH25100
0,50 x 40 mm	25 G x 1 1/2"	orange	CH25112
0,55 x 25 mm	24 G x 1"	purple	CH24100
0,55 x 38 mm	24 G x 1 1/2"	purple	CH24112
0,60 x 16 mm	23 G x 5/8"	blue	CH23058
0,60 x 25 mm	23 G x 1"	blue	CH23100
0,60 x 30 mm	23 G x 1 1/4"	blue	CH23114
0,60 x 40 mm	23 G x 1 1/2"	blue	CH23112
0,60 x 60 mm	23 G x 2 1/4"	blue	CH23214
0,70 x 25 mm	22 G x 1"	black	CH22100
0,70 x 30 mm	22 G x 1 1/4"	black	CH22114
0,70 x 35 mm	22 G x 1 2/5"	black	CH22125
0,70 x 40 mm	22 G x 1 1/2"	black	CH22112
0,70 x 50 mm	22 G x 2"	black	CH22200
0,80 x 16 mm	21 G x 5/8"	green	CH21058
0,80 x 25 mm	21 G x 1"	green	CH21100

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Size metric	Size G/"	Color code	Item Code
0,80 x 30 mm	21 G x 1 1/4"	green	CH21114
0,80 x 40 mm	21 G x 1 1/2"	green	CH21112
0,80 x 50 mm	21 G x 2"	green	CH21200
0,90 x 25 mm	20 G x 1"	yellow	CH20100
0,90 x 30 mm	20 G x 1 1/4"	yellow	CH20114
0,90 x 40 mm	20 G x 1 1/2"	yellow	CH20112
0,90 x 50 mm	20 G x 2"	yellow	CH20200
1,10 x 25 mm	19 G x 1"	ivory	CH19100
1,10 x 30 mm	19 G x 1 1/4"	ivory	CH19114
1,10 x 40 mm	19 G x 1 1/2"	ivory	CH19112
1,10 x 50 mm	19 G x 2"	ivory	CH19200
1,20 x 25 mm	18 G x 1"	pink	CH18100
1,20 x 40 mm	18 G x 1 1/2"	pink	CH18112
1,20 x 50 mm	18 G x 2"	pink	CH18200
1,50 x 50 mm	17 G x 2"	red purple	CH17200
1,60 x 25 mm	16 G x 1"	white	CH16100
1,60 x 40 mm	16 G x 1 1/2"	white	CH16112
1,80 x 40 mm	15 G x 1 1/2"	blue grey	CH15112

✓ intended for intramuscular, subcutaneous, intravenous and intra-arterial application

✓ possibility of short bevel lancet point grinding

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Created by: Miroslav Koštrna (Technologist)

Checked by: PaedDr. Zdenka Klbečková (Regulatory Affairs Manager)

Approved by: Ing. Peter Volár (Technical Manager)

Rastislav Broska, PhD. (Quality Manager)

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I. SCOPE AND APPLICATION

Product name: STERILE HYPODERMIC NEEDLE FOR SINGLE USE.

Intended purpose: Sterile hypodermic needle for single use is intended for injection and taking off a blood and other liquids at patients.

Trade-mark: MEDOJECT® **abbreviation:** JII

Product classification: based on MDR 2017/745, Annex VIII as **Class IIa, based on Rule 6**

Compatible devices:

Medical devices with connectors according to standard EN ISO 80369-7:2021.

Sterile hypodermic needle for single use is commonly used with Sterile hypodermic syringe for single use which is attached on the connector of the needle.

Sterile hypodermic syringes for single use are produced according to standard EN ISO 7886-1:2018 *Sterile hypodermic syringes for single use - Part 1: Syringes for manual use*.

These products are not accessories / parts of our product Sterile hypodermic needle for single use, but available is product Sterile injection set for single use, where syringe with needle is packed in various combinations.

II. PRODUCT VARIANTS

Sterile hypodermic needle for single use sizes and hub colour coding:

Size (mm)	Size (gauge)	Hub colour	Size (mm)	Size (gauge)	Hub colour	Size (mm)	Size (gauge)	Hub colour
0,3 x 12	30G x 1/2"	light yellow	0,6 x 25	23G x 1"	blue	1,1 x 50	19G x 2"	ivory
0,3 x 25	30G x 1"	light yellow	0,6 x 30	23G x 1 1/4"	blue	1,2 x 25	18G x 1"	pink
0,3 x 40	30 G x 1 1/2"	light yellow	0,6 x 40	23G x 1 1/2"	blue	1,2 x 38	18G x 1 1/2"	pink
0,33 x 12	29G x 1/2"	red	0,6 x 60	23G x 2 1/4"	blue	1,2 x 40	18G x 1 1/2"	pink
0,33 x 25	29G x 1"	red	0,6 x 80	23 G x 3 1/8"	blue	1,2 x 50	18G x 2"	pink
0,33 x 40	29 G x 1 1/2"	red	0,7 x 30	22G x 1 1/4"	black	1,2 x 70	18 G x 2 4/5"	pink
0,4 x 12	27G x 1/2 "	grey	0,7 x 35	22G x 1 2/5"	black	1,2 x 100	18 G x 4"	pink
0,4 x 16	27G x 5/8"	grey	0,7 x 40	22G x 1 1/4"	black	1,5 x 50	17G x 2"	red-purple
0,4 x 20	27G x 4/5"	grey	0,7 x 50	22G x 2"	black	1,5 x 100	17G x 4"	red-purple
0,4 x 20	27G x 3/4"	grey	0,7 x 90	22 G x 3 5/8"	black	1,6 x 15	16G x 5/8"	white
0,4 x 40	27G x 1 1/2"	grey	0,8 x 16	21G x 5/8"	green	1,6 x 25	16G x 1"	white
0,45 x 12	26G x 1/2"	brown	0,8 x 25	21G x 1"	green	1,6 x 35	16G x 1 2/5"	white
0,45 x 16	26G x 5/8"	brown	0,8 x 30	21G x 1 1/4"	green	1,6 x 40	16G x 1 1/2"	white
0,45 x 20	26G x 4/5"	brown	0,8 x 40	21G x 1 1/2"	green	1,6 x 70	16 G x 2 4/5"	white
0,45 x 25	26G x 1"	brown	0,8 x 50	21G x 2"	green	1,6 x 110	16 G x 4 3/8"	white
0,45 x 40	26G x 1 1/2"	brown	0,8 x 100	21 G x 4"	green	1,8 x 30	15G x 1 1/4"	blue-grey
0,5 x 16	25G x 5/8"	orange	0,8 x 120	21 G x 4 3/4"	green	1,8 x 40	15G x 1 1/2"	blue-grey
0,5 x 20	25G x 4/5"	orange	0,9 x 25	20G x 1"	yellow	1,8 x 70	15 G x 2 4/5"	blue-grey
0,5 x 25	25G x 1"	orange	0,9 x 30	20G x 1 1/4"	yellow	1,8 x 110	15 G x 4 3/8"	blue-grey
0,5 x 40	25G x 1 1/2"	orange	0,9 x 38	20G x 1 1/2"	yellow	2,0 x 30	14G x 1 1/4"	pale green
0,5 x 42	25G x 1 5/8"	orange	0,9 x 40	20G x 1 1/2"	yellow	2,0 x 70	14 G x 2 4/5"	pale green

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0,5 x 60	25G x 2 1/4"	orange	0,9 x 50	20G x 2"	yellow	2,0 x 80	14 G x 3 1/8"	pale green
0,55 x 25	24G x 1"	purple	0,9 x 70	20 G x 2 4/5"	yellow	2,0 x 100	14 G x 4"	pale green
0,55 x 38	24G x 1 1/2"	purple	1,1 x 25	19G x 1"	ivory	2,0 x 120	14 G x 4 3/4"	pale green
0,55 x 40	24G x 1 1/2"	purple	1,1 x 30	19G x 1 1/4"	ivory	2,1 x 40	14G x 1 1/2"	pale green
0,6 x 16	23G x 5/8"	blue	1,1 x 40	19G x 1 1/2"	ivory	2,1 x 120	14 G x 4 3/4"	pale green

III. TECHNICAL DATA

III.1. General requirements (EN ISO 7864:2016, art. 4):

Cleanness general:

- a/ The surface of the hypodermic needle tube and hub socket (fluid path surface) is free from particles and extraneous matter. (EN ISO 7864:2016, art.4.3). Inspection is performed by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx (the surface of the hypodermic needle tube) and under 2,5× magnification (the hub socket (fluid path surface)).

Acidity / alkalinity:

- b/ The pH value of the needle prepared extract fluid is within one pH unit of the pH value of the control fluid. (EN ISO 7864:2016, art.4.4).

Extractable metals:

- c/ Content of metals is not more than a combined total of 5 mg/l of lead, tin, zinc and iron; the cadmium content is less than 0,1 mg/l. (EN ISO 7864:2016, art.4.5).
- d/ Size of hypodermic needle is marked by outer nominal diameter of the cannula and by nominal length of the cannula. Indications are given in millimeters [mm] and simultaneously in measure gauge [G]. Wall thickness is indicated by an abbreviation (RW, TW, ETW, UTW). (EN ISO 7864:2016, art.4.6).
- e/ Outer nominal diameter of hypodermic needle is defined by color coding according to EN ISO 6009:2016 used on hub of the needle. (EN ISO 7864:2016, art.4.7) – see point II.

Production takes place in clean rooms class ISO8 / ISO9 acc. to standard EN ISO 14644-1:2015.

JII resist changes in temperature from 0°C to +40°C without any material change.

III.2. Needle hub (EN ISO 7864:2016, art. 4.8):

- a/ Conic of needle hub oblige to standard EN ISO 80369-1:2018 and EN ISO 80369-7:2021.
- b/ The hub of the needle has regular shape without deformations and is smooth.
- c/ The needle hub is pigmented and color comply with EN ISO 6009:2016.

III.3. Needle protective cap = cover (EN ISO 7864:2016, art. 4.9):

- a/ The needle protective cover (cap) is unpigmented, from transparent material.
- b/ Protective cap allows putting needle on the cone of the syringe reliably without needle contamination danger and at cap scanning the needle do not remove from the cone of the syringe.

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c/ Pull-out force between the protective cap and the needle hub is max. 15N.

III.4. Needle tube = cannula (EN ISO 7864:2016, art. 4.10):

a/ Cannula is made of tube according to EN ISO 9626:2016 (EN ISO 7864:2016, art.4.10.1).

b/ Actual length of cannula is equivalent to nominal length in tolerance mentioned in the table (EN ISO 7864:2016, art.4.10.2, table 1):

Dimensions in millimetres	
Nominal length of needle tube	Tolerance
<25	+1 -2
25 to 39	+1,5 -2,5
40	0 -4
>40	+1,5 -2,5

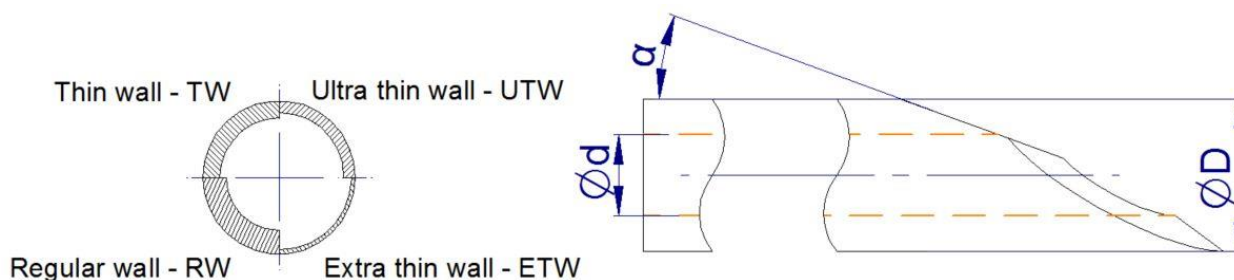
c/ The outer surface of cannula shall be smooth and glossy, without scratches, cracks and scores visible under normal vision. Inner slit of cannula shall be free from all dirt and it is ensured its trafficability. (EN ISO 7864:2016, art.4.10.3).

d/ Cannula is straight with regular cut and thickness of wall.

e/ Silicone (lubricant) is not eye visible or visible with the help of glasses in drop fluid form on outer / inner surface of cannula. Lubricant is polydimethylsiloxane which quantity does not exceed 0,25mg/cm² of the lubricated surface area of the needle tube (EN ISO 7864:2016, art.4.10.4).

III.5. Needle point (EN ISO 7864:2016, art. 4.11):

a/ The needle point is sharp and free from edges, burrs and hooks.



Picture: Needle point

b/ The needle point is designated so as to minimize coring and fragmentation when penetrating vial closures.

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III.6. Bond between hub and needle tube (EN ISO 7864:2016, art. 4.12):

- a/ Cannula is joint firmly and airtight with hub, glue ensures that joint don't leak on hub and also don't penetrate inside conical part of hub.
- b/ The connection of hub and needle tube withstand (no broken, disconnection) the minimal force defined in the table for specific outer diameter of cannula:

Designated metric size of needle mm	Force min. N
0,18	11
0,2	11
0,23	11
0,25	11
0,3	11
0,33	22
0,36	22
0,4	22
0,45	22
0,5	22
0,55	34
0,6	34
0,7	40
0,8	44
0,9	54
1,1	69
1,2	69

III.7. Patency of lumen (EN ISO 7864:2016, art. 4.13):

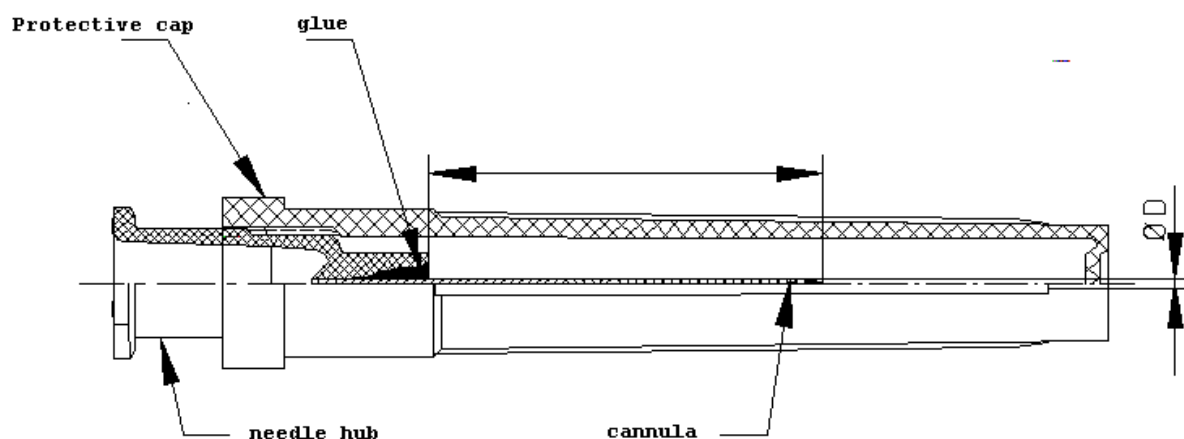
- a/ Depending on the needle size and geometry of the needle, patency of lumen is determined by stainless steel stylet of the appropriate diameter selected acc. to the table, when this stylet must pass through the needle.

Dimensions in millimetres

Designated metric size of needle	Outer diameter of stylet			
	for needle of regular walled tubing	for needle of thin- walled tubing	for needle of extra- thin-walled tubing	for needle of ultra-thin- walled tubing
0,30	0,11	0,13	0,15	0,19
0,33	0,11	0,15	0,19	0,21
0,36	0,11	0,15	-	-
0,4	0,15	0,19	-	-
0,45	0,18	0,23	-	-
0,5	0,18	0,23	-	-
0,55	0,22	0,27	-	-
0,6	0,25	0,29	0,30	-
0,7	0,30	0,35	0,37	-
0,8	0,40	0,42	0,44	-
0,9	0,48	0,49	0,50	-
1,1	0,58	0,60	0,68	-
1,2	0,70	0,73	0,83	-

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III.8. Needle sketch



Picture. 1: Hypodermic needle

III.9. Materials

Material used by production of Sterile hypodermic needles for single use:

<i>Needle Part</i>	<i>Type of the material</i>
Needle hub	Polypropylene + Colour Masterbatch
Cannula	Stainless steel
Protective cap = cover	Polyethylene / Polypropylene
Silicone oil	Polydimethyl siloxane
Glue	Epoxy glue

Sterile hypodermic needles for single use are made from medical harmless materials and comply with requirements of standard EN ISO 10993-1:2020 and related biocompatibility tests according to product characterization. JII fulfil requirements of EN ISO 7864:2016 and EN ISO 9626:2016.

III.10. Sterilization

Sterile hypodermic needles for single use are sterilized by ethylene oxide in their final package using validated sterilization process (EN ISO 11135:2014) ensuring SAL at least 10^{-6} (EN 556-1:2001).

III.11. Shelf-life

The package of the Sterile hypodermic needles for single use and its integrity ensures the sterility and usability for the period of 5 years provided the transport and storage fulfil conditions according to Chapter VIII.

IV. PACKAGING

Sterile hypodermic needles for single use are packed in unit package (blister packaging), which guarantee sterility for five years and are designed for single use only. Package is made of thermoformable foil and medical paper. Opening of the unit package is based peel-back, which

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ensure immediate and safe use during application. JII are afterwards packed in box (secondary packaging) and finally in the shipping package used like storage and transport packaging.

- Packaging materials are free from holes, rips, folds and foreign objects.
- Properties of foil / paper are in accordance with EN ISO 868-5:2018 / EN 868-6:2017.
- Materials for packages and labels:

<i>Part of the packaging</i>	<i>Material package</i>
Unit package (blister)	Paper and thermoformable foil
Secondary package (box)	Smooth cardboard
Shipping package (carton)	Corrugated cardboard
Shipping package label	Paper label - sticker
Shipping package tape	Self-adhesive tape

- Dimensions and quantities in package:

<i>Size (mm)</i>	<i>Size (gauge)</i>	<i>Hub colour</i>	<i>Pieces in box</i>	<i>Box dimensions (mm)</i>	<i>Pieces in shipping package</i>	<i>Shipping package dimensions (mm)</i>	<i>Model</i>
0,3 x 12	30G x 1/2"	light yellow	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,3 x 25	30 G x 1"	light yellow	100	110 x 77 x 86	4 000	460 x 400 x 190	D
0,3 x 40	30 G x 1 1/2"	light yellow	100	110 x 77 x 86	4 000	460 x 400 x 190	D
0,33 x 12	29G x 1/2"	red	100	110 x 77 x 86	4 000	460 x 400 x 190	D
0,33 x 25	29 G x 1"	red	100	110 x 77 x 86	4 000	460 x 400 x 190	D
0,33 x 40	29 G x 1 1/2"	red	100	110 x 77 x 86	4 000	460 x 400 x 190	D
0,4 x 12	27G x 1/2 "	grey	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,4 x 16	27 G x 5/8"	grey	100	110 x 77 x 86	4 000	460 x 400 x 190	D
0,4 x 20	27G x 4/5"	grey	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,4 x 20	27G x 3/4"	grey	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,4 x 40	27G x 1 1/2"	grey	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,45 x 12	26G x 1/2"	brown	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,45 x 16	26G x 5/8"	brown	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,45 x 20	26 G x 4/5"	brown	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,45 x 25	26G x 1"	brown	100	100 x 85 x 88 / 110 x 77 x 86	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,45 x 40	26G x 1 1/2"	brown	100	110 x 77 x 86	4 000	460 x 400 x 190	D
0,5 x 16	25G x 5/8"	orange	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,5 x 20	25G x 4/5"	orange	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,5 x 25	25G x 1"	orange	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,5 x 40	25G x 1 1/2"	orange	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,5 x 42	25G x 5/8"	orange	100	110 x 77 x 100	4 000	460 x 400 x 190	D
0,55 x 25	24G x 1"	purple	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,55 x 38	24G x 1 1/2"	purple	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,55 x 40	24G x 1 1/2"	purple	100	110 x 77 x 100	4 000	460 x 400 x 190	D


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0,6 x16	23G x5/8"	blue	100	110 x 77 x 100	4 000	460 x 400 x 190	D
0,6 x 25	23G x 1"	blue	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,6 x 30	23G x 1 1/4"	blue	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,6 x 40	23G x 1 1/2"	blue	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,6 x 60	23G x 2 1/4"	blue	100	110 x 77 x 100	1 000	460 x 400 x 190	D
0,6 x 80	23 G x 3 1/8"	blue	100	208 x 170 x 75	2 000	430 x 390 x 365	B
0,7 x 25	22G x 1"	black	100	100 x 85 x 88	4 000	415 x 440 x 190	C
0,7 x 30	22G x 1 1/4"	black	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,7 x 35	22G x 1 2/5"	black	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,7 x 40	22G x 1 1/2"	black	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,7 x 50	22G x 2"	black	100	110 x 85 x 88 / 110 x 77 x 100	4 000	454 x 440 x 190 / 110 x 77 x 100	C / D
0,7 x 90	22 G x 3 5/8"	black	100	215 x 160 x 85	1 000	450 x 340 x 230	B
0,8 x 16	21G x5/8"	green	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,8 x 25	21G x 1"	green	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,8 x 30	21G x 1 1/4"	green	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,8 x 40	21G x 1 1/2"	green	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,8 x 50	21G x 2"	green	100	110 x 85 x 88	4 000	454 x 440 x 190	C
0,8 x 100	21 G x 4"	green	100	208 x 170 x 75	2 000	430 x 390 x 365	B
0,8 x 120	21 G x 4 3/4"	green	100	208 x 170 x 75	2 000	430 x 390 x 365	B
0,9 x 25	20G x 1"	yellow	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,9 x 30	20G x 1 1/4"	yellow	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,9 x 38	20 G x 1 1/2"	yellow	100	100 x 95 x 90	4 000	520 x 400 x 200	B
0,9 x 40	20G x 1 1/2"	yellow	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
0,9 x 50	20G x 2"	yellow	100	110 x 85 x 88	4 000	454 x 440 x 190	C
0,9 x 70	20 G x 2 4/5"	yellow	100	114 x 98 x 127	3 000	510 x 245 x 365	B
1,1 x 25	19G x 1"	Ivory	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,1 x 30	19G x 1 1/4"	Ivory	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,1 x 40	19G x 1 1/2"	Ivory	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,1 x 50	19G x 2"	Ivory	100	110 x 77 x 100	4 000	460 x 400 x 220	D
1,2 x 25	18G x 1"	Pink	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,2 x 38	18 G x 1 1/2"	Pink	100	100 x 85 x 88	4 000	415 x 440 x 190	C
1,2 x 40	18G x 1 1/2"	Pink	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,2 x 50	18G x 2"	pink	100	110 x 85 x 88	4 000	454 x 440 x 190	C
1,2 x 70	18 G x 2 4/5"	pink	100	114 x 98 x 127	3 000	510 x 245 x 365	B
1,2 x 100	18 G x 4"	pink	100	215 x 160 x 85	1 000	450 x 340 x 230	B
1,5 x 50	17G x 2"	red-purple	100	110 x 101 x 75 110 x 77 x100	3 000 4 000	395 x 235 x 330 460x 400 x 220	B / D
1,5 x 100	17G x 4"	red-purple	100	215 x 160 x 85	1 000	450 x 340 x 230	B
1,6 x 15	16G x 5/8"	white	100	100 x 85 x 88 /	4 000	415 x 440 x 190 /	C / D

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				110 x 77 x 100		460 x 400 x 190	
1,6 x 25	16G x 1"	white	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,6 x 35	16 G x 1 2/5"	white	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,6 x 40	16G x 1 1/2"	white	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,6 x 70	16 G x 2 4/5"	white	100	215 x 160 x 85	1 000	450 x 340 x 230	B
1,6 x 110	16 G x 4 3/8"	white	100	215 x 160 x 85	1 000	450 x 340 x 230	B
1,8 x 30	15G x 1 1/4"	blue-grey	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,8 x 40	15G x 1 1/2"	blue-grey	100	100 x 85 x 88 / 110 x 77 x 100	4 000	415 x 440 x 190 / 460 x 400 x 190	C / D
1,8 x 70	15 G x 2 4/5"	blue-grey	100	114 x 98 x 127	3 000	510 x 245 x 365	B
1,8 x 110	15 G x 4 3/8"	blue-grey	100	215 x 160 x 85	1 000	450 x 340 x 230	B
2,0 x 30	14G x 1 1/4"	pale green	100	110 x 77 x 100	4 000	460 x 400 x 190	D
2,0 x 70	14 G x 2 4/5"	pale green	100	215 x 160 x 85	1 000	450 x 340 x 230	B
2,0 x 80	14 G x 3 1/8"	pale green	100	215 x 160 x 85	1 000	450 x 340 x 230	B
2,0 x 100	14 G x 4"	pale green	100	215 x 160 x 85	1 000	450 x 340 x 230	B
2,0 x 120	14 G x 4 3/4"	pale green	100	215 x 178 x 85	1 000	450 x 375 x 230	B
2,1 x 40	14G x 1 1/2"	pale green	100	110 x 77 x 100	4 000	460 x 400 x 190	D
2,1 x 120	14 G x 4 3/4"	pale green	100	215 x 178 x 85	1 000	450 x 375 x 230	B

V. PRODUCT IDENTIFICATION

a) The product is identified by product name, size, and lot number (LOT).

Lot number of the products is in this format: **YY DDD/NNNN**

where: YY are the last two digits of the year

DDD is day in the year (001-365)

NNNN is a sequential sterilization number in the year (0001, 0002...)

or in format: **YYMMDD / YYMMDDXXX**

where: YY are last two numbers of the year production

MM is month (1-12)

DD is day (1-31)

XXX is specific code

b/ Date of production in this format: **YYYY-MM**

where: YYYY is year of production

MM is month of production (01-12)

VI. TESTS AND INSPECTION

a/ General inspection (SOP 4110, SOP 4212, SOP 4214)

b/ Data on the packaging (SOP 4113, SOP 4405, EN ISO 7864:2016, art.6)

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- c/ Adhesive tensile strength test paper - foil (weld quality of packaging unit) (SOP 4405, EN 868-5:2018)
- d/ Airtightness of the package (SOP 4405)
- e/ Penetration of printing color (SOP 4405)
- f/ Test of cannula dimensions (EN ISO 7864:2016, EN ISO 9626:2016)
- g/ Test of the sharpness of needle point (SOP 4214, SOP 4405)
- h/ Needle (cannula) cleanness (EN ISO 7864:2016, art.4.3)
- i/ Transparency (visual control) (SOP 4405)
- j/ Cone dimension test (SOP 4405)
- k/ Test of the tightness of the cone of the syringe and the joint of cannula with hub (SOP 4214, SOP 4405)
- l/ Passage of cannula after assembly (EN ISO 7864:2016, art.4.13, table 3)
- m/ Strength of the joint between hub and cannula (EN ISO 7864:2016, table 2, Annex E)
- m/ Penetration force (EN ISO 7864:2016, Annex D)
- o/ cannula tests
 - Stiffness of tubing (EN ISO 9626:2016, art.5.8, Annex B)
 - Resistance of tubing to breakage (EN ISO 9626:2016, art.5.9, Annex C)
 - Sharpness of cannula tip (EN ISO 7864:2016)
 - Shape and size of cannula (EN ISO 7864:2016)
 - Resistance to corrosion (EN ISO 7864:2016)
- p/ chemical tests:
 - Limits for acidity or alkalinity (EN ISO 7864:2016)
 - Limits for extractable metals (EN ISO 7864:2016)
- q/ biological tests – sterility, pyrogenity, haemolysis, bioburden (EN ISO 10993-1:2020, European Pharmacopoeia, SOP 4420, SOP 4421, SOP 4424, SOP 4430)

VII. DELIVERY, WARRANTY

- a) Deliveries are inspected after agreement with the customer by statistical acceptance criteria according to ISO 2859-1:1999.
- b) With each delivery, it is possible (according to customer requirement) to issue Certificate of quality and sterility.
- c) The manufacturer grants the guarantee for the period of usability of the product for 5 years, provided the prescribed transport and storage conditions according to Chapter VIII are fulfilled.
- d) Period of usability (expiration) is marked on packaging with form:

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⌚ **YYYY - MM** where: YYYY is last year of usability

MM is the last month of usability (01-12)

VIII. TRANSPORT, STORAGE

- a) The transport of the packed Sterile hypodermic needles for single use can be carried out only in covered, clean and dry means of transport at the temperature between 0°C to +40°C. Warning data marked on the package during the transport must be obeyed.
- b) When shipped overseas you must comply with the following requirements:
 - Packaging must be of a quality and durability that is able to withstand operating conditions in standard shipping containers.
 - It is necessary for packaging to prevent any loss of packed goods.
 - Packages on palette must be sufficiently wrapped and banded.
 - A wooden container used for packaging must be fumigated, or it may be packed in plastic or particleboard pallets.
- c) Sterile hypodermic needles for single use must be stored in dry, ventilated, dust-free, dark rooms at the temperature within the range from 0°C to +40°C. No organic solvents and chemicals are allowed to be stored with the Sterile hypodermic needles for single use. Sterile hypodermic needles for single use can be stored in the shipping containers in up to eight layers lying on each other.