TABLE OF CONTENTS

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I. SCOPE AND APPLICATION

Product name: INSULIN SYRINGES FOR SINGLE USE

Intended use: for the administration of 1 ml; 0,5ml or 0,3 ml, that is 100, 50 or 30 units of U 100 insulin, or 1ml of 40 units of U 40 Insulin.

Trade-mark: CHIRANA

Product classification: based on MDD 93/42/EEC Annex IX amended by Directive 2007/47/EC as **Class IIa, based on Rule 6**

II. PRODUCT VARIANTS

Insulin syringes with integrated needle:

Nominal volume (ml)	Type	Cannula dimension (mm)	Needle sheath color*
0,3; 0,5; 1	U 100	0,4 x 4, 6, 8, 10, 12, 12.7, 13 27G x 5/32“, 4/16”,5/16”, 3/8“, 1/2”, 1/2”	Orange
		0,36 x 4, 6, 8, 10, 12, 12.7, 13 28G x 5/32“, 4/16”,5/16”, 3/8“, 1/2”, 1/2”	
		0,33 x 4, 6, 8, 10, 12, 12.7, 13 29G x 5/32“, 4/16”,5/16”, 3/8“, 1/2”, 1/2”	
		0,3 x 4, 6, 8, 10, 12, 12.7, 13 30G x 5/32“, 4/16”,5/16”, 3/8“, 1/2”, 1/2”	
		0,25 x 4, 6, 8, 10, 12, 12.7, 13 31G x 5/32“, 4/16”,5/16”, 3/8“, 1/2”, 1/2”	
		0,23 x 4, 6, 8, 10, 12, 12.7, 13 32G x 5/32“, 4/16”,5/16”, 3/8“, 1/2”, 1/2”	
		0,2 x 4, 6, 8, 10, 12, 12.7, 13 33G x 5/32“, 4/16”,5/16”, 3/8“, 1/2”, 1/2”	
1	U 40	0,33 x 4, 6, 8, 10, 12, 12.7, 13 29G x 5/32“, 4/16”,5/16”, 3/8“, 1/2”, 1/2”	Red

Insulin syringes LUER:

Nominal volume (ml)	Type	Needle sheath color*
1	U 100	Orange
1	U 40	Red

* The colour coding of needle sheath (cap) indicate insulin concentration and comply with EN ISO 8537:2016, art. 5.3.

III. TECHNICAL DATA

III.1. General

a/ Types of syringes: (EN ISO 8537:2016, art. 4)

- Type 1: syringe having a 6 % (Luer) male conical fitting, supplied with no needle and packaged in unit packaging.
- Type 3: syringe having a 6 % (Luer) male conical fitting, and supplied with a detached or detachable needle and packaged in a unit packaging.
- Type 5: syringe having a fitting other than a 6 % (Luer) taper, supplied with a needle not intended to be detached and packaged in a unit packaging.
- Type 6: syringe having a fitting other than a 6 % (Luer) taper, supplied with a needle not intended to be detached and fitted with protective caps and packaged.

b/ Nominal volume size of 1 ml, 0.5 ml or 0.3 ml, defines EN ISO 8537:2016. Nominal volume of 1 ml (0.5 ml) corresponds to 40 units of insulin U 40, or nominal volume of 1 ml (0.5 ml, 0.3 ml) corresponds to 100 units of insulin U 100. Tolerance on graduated volume are listed in the table:

Unit scale	Nominal volume (ml)	Minimal length of scale (mm)	Scale interval (units)	Tolerance on graduated volume	
				Volumes less than half the nominal capacity	Volumes equal to or greater than half the nominal volume
U 40	1	50	1	±1,5% of the nominal volume +2% of the expelled volume	±5% of the expelled volume
U 40	0,5	43	1 / 0,5		
U 100	1	57	2 / 1		
U 100	0,5	43	1		
U 100	0,3	41	1 / 0,5		

c/ The barrel length shall be such that the syringe has a usable capacity of either 10 % more than the nominal capacity or 3 mm of plunger travel beyond the scale marking, whichever is less. (EN ISO 8537:2016, art. 5.6.1)

d/ Connection between the piston and the piston seal is such that no water leakage occurs past the piston seal. (EN ISO 8537:2016, Annex E)

e/ Connection between the barrel and hub is such that no water leakage occurs.

III.2. Design

a) Syringe barrel is sufficiently transparent. During the filling of syringe with vaccine even small bubbles of air are visible.

b) The syringe and needle are free from defects affecting safety, serviceability for their intended use, and appearance.

c) The nominal capacity of the syringe shall be designated in milliliters (ml).

d) The inner surface of the barrel of the syringe is smooth and glossy. From the side of the flange it has a piston stop, which prevents the piston from being pulled out of the barrel without applying excessive force.

e) The surface of the barrels, pistons and gaskets of syringes is without piping, sharp edges, cracks, surface inclusions and dark specks of the material.

f) The open end of the barrel shall be provided with finger grips that prevent the syringe from rolling when the axis of the barrel is placed perpendicular to the incline of a flat surface angled at 10° from horizontal. (EN ISO 8537:2016, art. 5.6.2)

g) Dead space is minimized to reduce waste and transmission of infectious agents. The dead space does not exceed the limits (EN ISO 8537:2016, art. 5.11.1):

Type of syringe	Maximum dead space (ml)
1 and 2	0,07
3 and 4	0,10
5 and 6	0,02

III.3. Extraneous matter (EN ISO 8537:2016, art. 5.4, 5.5):

Cleanness general:

a/ The surface of the syringe that come in contact with injection fluids during normal use is free from particles and extraneous matter.

Acidity / alkalinity:

b/ The pH value of the syringe assessment fluid is within one pH unit of the pH value of the control fluid.

Extractable metals:

c/ Content of metals is not more than a combined total of 5 mg/kg of lead, tin, zinc and iron; the cadmium content is less than 0,1 mg/kg.

Lubrication:

d/ Lubricant shall not form pools of fluid on the interior surface of the syringe. Lubricant shall not be visible to an individual with normal or corrected-to-normal vision as droplets of fluid on the outside surface of the needle tube.

Production takes place in clean rooms class ISO8.

III.4. Nozzle (EN ISO 8537:2016, art. 5.8)

a) The male conical fitting of the syringe nozzle on syringe types 1, 2, 3 and 4 shall comply with the requirements of ISO 594-1. (EN ISO 8537:2016, art. 5.8.1)

b) The syringe nozzle shall be situated centrally, i.e. shall be co-axial with the barrel. (EN ISO 8537:2016, art. 5.8.2)

III.5. Scale (EN ISO 8537:2016, Annex H)

a) The scale and scale numbers are legible and of a color that contrasts clearly with the syringe.

b) The graduation lines are of a uniform thickness between 0,2 mm and 0,4 mm.

c) The length of the short graduation lines is approximately half the length of the long graduation lines.

d) The graduation lines are numbered

- at every five units for the 0,3 ml and 0,5 ml syringes, and
- at every 10 units for the 1 ml syringe.

e) The height of the numbers should be at least 3 mm.

III.6. Cannula, Needle (EN ISO 8537:2016, art. 5.9, EN ISO 7864:2016, EN ISO 9626:2016)

a) Outer surface of the cannula is smooth, glossy, without visible scratches or cracks. Inner surface of cannula is free from all dirt and it is passable.

b) The cannula is made from tubes according to EN ISO 9626:2016

c) The dimensions of tubing are according to EN ISO 9626:2016

d) Cannula is straight with regular cut and wall thickness.

e) The cannula is connected coaxially with the hub. Permitted deviation of cannula axis from hub axis is 3 °.

f) Cannula is joint firmly and airtight with hub, glue ensures that joint do not leak on hub and also do not penetrate inside conical part of hub.

g) The cannula is connected with the hub airtight. Glue ensures bond. Glue doesn't leak on the hub or into conical part of hub.

h) The bond between the hub and needle tube shall withstand the force at least:

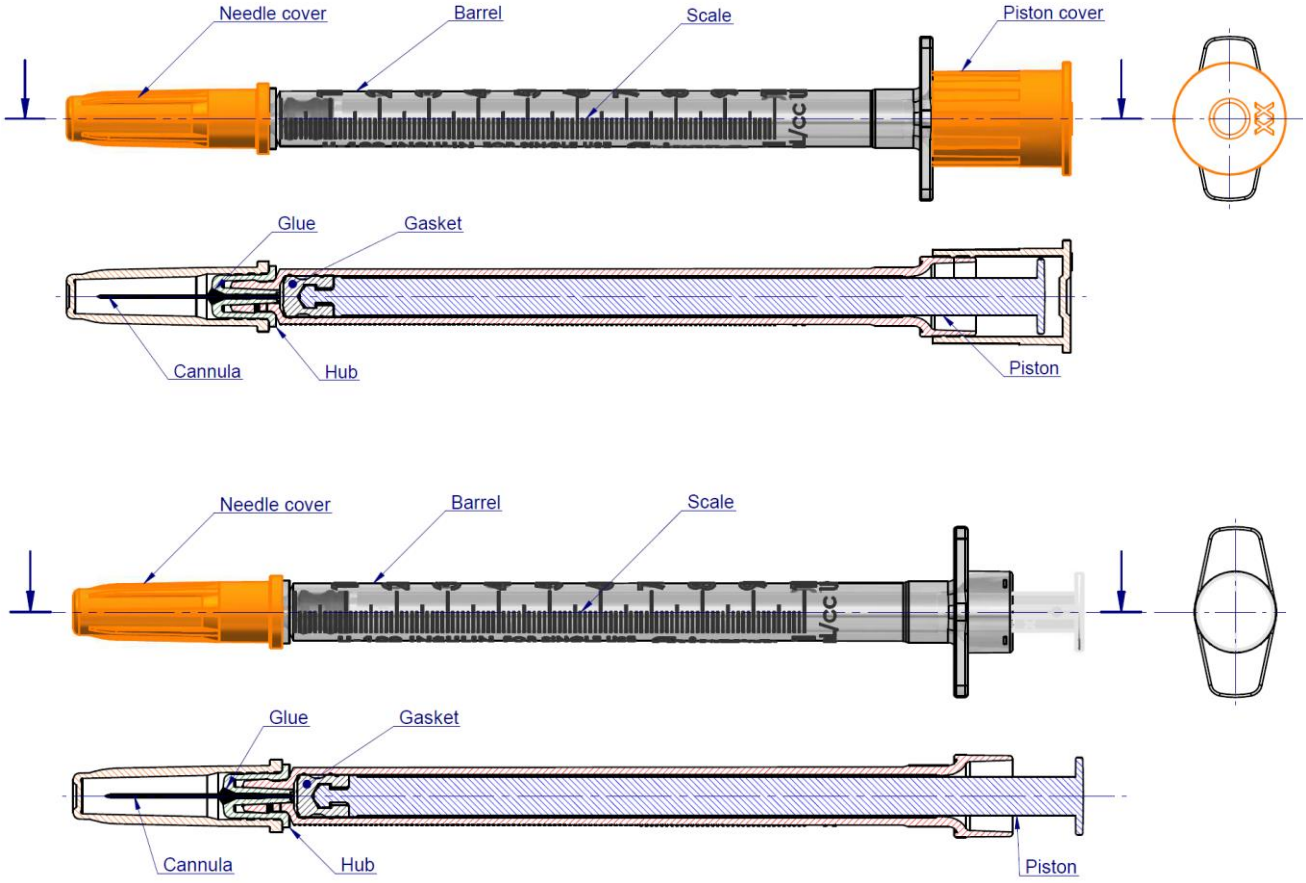
Outside diameter of needle (mm)	Minimum shearing strength (N)
≥ 0,33	22N
< 0,33	11N

i) Silicone coated on the outer or inner surface of the cannula is not visible by normal or corrected-to-normal vision in form of droplets.

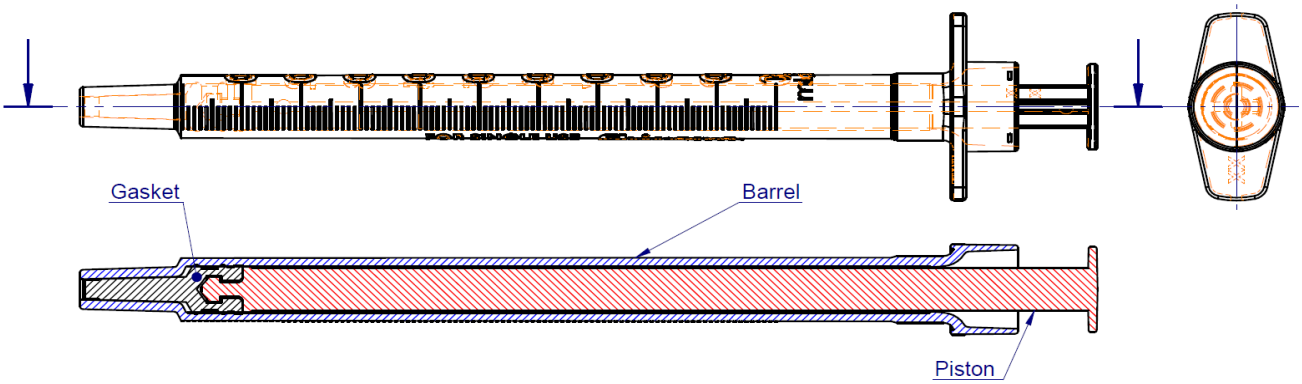
j) When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the cannula appears free from particles and extraneous matter.

k) Needles for syringe types 3 and 4 are in accordance with EN ISO 7864:2016. Needle tubing for syringe types 5 and 6 are in accordance with EN ISO 9626:2016 and needle point in accordance with EN ISO 7864:2016.

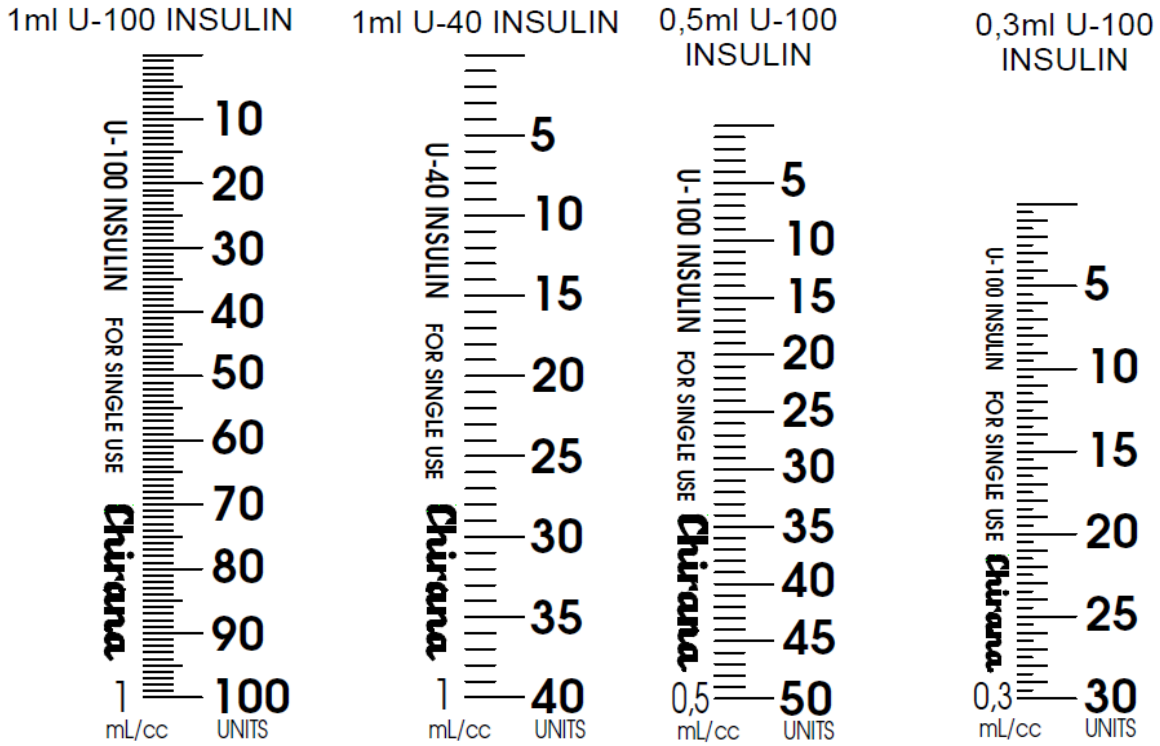
III.7. Syringe sketch



Picture. 1: Insulin syringe for single use (Type 5 or 6)



Picture.2: Insulin syringe for single use-Luer (Type 1 and 3)



Picture. 3 Scales U 100 (1ml; 0,5ml; 0,3ml) and U 40 (1ml)

III.8. Materials

Material used by production of insulin syringes:

Part	Material
Barrel	Polypropylene
Piston	Impact Polystyrene
Gasket	Synthetic rubber (LATEX FREE)
Hub	Polypropylene
Cannula	Stainless steel
Cover for cannula	polyethylene + colour masterbatch
Cover for piston	polyethylene + colour masterbatch
Glue	UV glue
Silicone oil	Polydimethyl siloxane
Scale	Paint, paint thinner

Insulin syringes are made from medical harmless materials and comply with requirements of standard EN ISO 10993-1:2009 and related biocompatibility tests acc. to product characterization.

III.9. Sterilization

Syringes 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.10. Shelf-life

The package of the syringe and its integrity ensure the sterility and usability for the period of 5 years provided the transport and storage fulfil conditions according to Chapter VIII.

IV. PACKAGING

Insulin syringes are packed in unit package, which guarantee sterility for five years and are designed for single use only. Package is made of transparent thermoformable foil and cover medical paper. Opening of the unit package is based on peel-back system, which ensure immediate and safe use during application. Another possible packaging is PE bag from thermoformable foil. Syringes are afterwards packed in box and shipping package used like storage and transport packaging.

a) Packaging materials are free from holes, rips, folds and foreign objects.

b) The weld width of blister is at least 5 mm.

c) Properties of foil / paper are in accordance with EN ISO 868-5:2009 / EN 868-6:2017.

d) Materials for packages and labels:

Part	***Material***
Unit package (blister)	Paper and thermoformable foil
Primary package (PE bag)	Thermoformable foil
Secondary package (box)	Smooth cardboard
Shipping package (carton)	Corrugated cardboard
Shipping package label	Paper label - sticker
Shipping package tape	Self-adhesive tape

e) Dimensions and quantities in package:

Size / type*	**Quantity in PE bag (pcs)**	**Quantity in box (pcs)**	**Box (mm)**	**Quantity in carton (pcs)**	**Carton (mm)**
Insulin syringe U40 (blister)	-	100	220x152x92	2000	780x380x235
Insulin syringe U100 (blister)	-	100	220x152x92	2000	780x380x235
Insulin syringe U40 (PE bag)	10	100	220x152x92	2000	780x380x235
Insulin syringe U100 (PE bag)	10	100	220x152x92	2000	780x380x235

* Insulin syringes may be packed in blister packaging (individually) or in PE bag.

V. PRODUCT IDENTIFICATION

a/ The product is identified by product name, nominal volume 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...)

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 / visual inspection (SOP 4810, SOP 4812, SOP 4813)

b) test of force required to operate piston (EN ISO 8537:2016, Annex. C)

c) test for air leakage past syringe piston during aspiration (EN ISO 8537:2016, Annex. B)

d) test method for liquid leakage at syringe piston and needle syringe nozzle / hub or needle / barrel under compression (EN ISO 8537:2016, Annex. E)

e) test of air leakage past nozzle / hub or needle / barrel during aspiration (EN ISO 8537:2016, Annex. F)

f) bond between hub and cannula (EN ISO 8537:2016)

g) Determination of acidity/alkalinity (EN ISO 8537:2016, Annex. A)

h) Determination of extractable metals (EN ISO 8537:2016, Annex. A)

i) Test of needle sharpness (SOP 4404)

j) nominal volume test (EN ISO 8537:2016 Annex D)

k) residual volume test (EN ISO 7886-1:2018, Annex C)

l) stability test against temperature changes (SOP 4404)

m) adhesive tensile strength test paper - foil (weld quality of packaging unit) (EN ISO 868-5:2009, SOP 4404)

n) test of airtightness of the package (SOP 4404)

o) penetration of printing color (SOP 4404)

p) color scale stability test (SOP 4404)

q) Cannula tests

- Stiffness of tubing (EN ISO 9626:2016)
- Resistance of tubing to breakage (EN ISO 9626:2016)
- Sharpness of cannula tip (EN ISO 7864:2016)
- Shape and size of cannula (EN ISO 7864:2016)
- Resistance to corrosion (EN ISO 9626:2016)
- Limits for acidity or alkalinity (EN ISO 7864:2016)
- Limits for extractable metals (EN ISO 7864:2016)

r) chemical tests (EuPh, EN ISO 8537:2016, SOP 4120)

s) biological tests (EN ISO 10993-1:2009, EuPh, SOP 4422, SOP 4424, SOP 4430)

t) sterility test (EuPh, SOP 4420)

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:

⌛ **YYYY MM** where: YYYY is last year of usability

MM is the last month of usability (1-12)

VIII. TRANSPORT, STORAGE

a) The transport of the packed insulin syringes 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) Syringes 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 syringes. Syringes can be stored in the shipping containers in up to eight layers lying on each other.