CONTENT

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I. SCOPE AND APPLICATION

Product name: STERILE PERFUSION SYRINGE FOR SINGLE USE

Intended purpose: Sterile Perfusion syringes for single use 20, 30, 50 ml are intended for drug application into human body via syringe pumps. Needle is for piercing the vials and bags and taking the drug into the syringe. Attached stopper is for temporarily closure of the syringe with prepared drug. Syringe opaque / black is for using with light sensitive drugs and solutions. Syringes can also be used for withdrawing fluids from human body or for administration of fluids into the human body.

Trade-mark: CHIRANA® / INFUJECT® / PERFUJECT®

Product classification: based on MDR 2017/745, Annex VIII as **Class IIa, based on Rule 2**

Compatible devices:

Medical devices with Luer-Lock connectors according to standard EN ISO 80369-7:2021 (e.g., needles, lines). These products are not accessories / parts of our product Sterile perfusion syringe for single use. Available are versions with attached needle (diameter 1,8 and 2,0mm), intended for piercing the vials and bags and taking the drug into the syringe.

II. PRODUCT VARIANTS

Product variants (models, sizes) for Sterile Perfusion syringe for single use:

20ml Perfusion syringe L-L
30ml Perfusion syringe L-L
50ml Perfusion syringe L-L
50ml Perfusion syringe L-L, F
50ml Perfusion syringe L-L, BB
20ml INFUJECT®
30ml INFUJECT®
50ml INFUJECT®
50ml PERFUJECT®

All variants can be in the following design:

- transparent / opaque / black
- without / with needle 1.8x30–110mm, 2.0x30–120mm
- without / with red stopper

III. TECHNICAL DATA

III.1. General

a/ Sterile Perfusion syringes for single use are produced and comply with requirements of EN ISO 7886-2:2020 and EN ISO 7886-1:2018.

Needle is produced and comply with requirements of EN ISO 7864:2016. Needle specification – acc. to TPF 310-0509-01 (JII bulk).

Stopper is produced and comply with standards EN ISO 80369-7:2017. Stopper (red color) specification – acc. to drawing no. INJ 730 0039 9.

b/ Nominal capacity of syringe complies with requirements of EN ISO 7886-2:2020 (and EN ISO 7886-1:2018).

Tolerance on graduated capacity (nominal capacity) is acc. to EN ISO 7886-2:2020, art.9 (EN ISO 7886-1:2018 art. 8, table 1):

Table no.1:

Nominal capacity of syringe V (ml)	***Minimum overall length of scale to nominal capacity mark (mm)***	***Max. dead space (ml)***	***Scale interval (ml)***	***Tolerance on any graduated capacity***	
				Less than half nominal capacity	***Equal, to or greater than half nominal capacity***
20 ≤ V < 30	52	0,15	2,0	± (1,5% of V + 1% of expelled volume)	± 4% of expelled volume
30 ≤ V < 50	67	0,17	2,0	± (1,5% of V + 1% of expelled volume)	± 4% of expelled volume
50 ≤ V	75	0,20	5,0	± (1,5% of V + 1% of expelled volume)	± 4% of expelled volume

c/ Dead space is minimized to reduce waste and transmission of infectious agents. The maximum volume of liquid contained in the barrel and the nozzle when the plunger stopper is fully inserted is acc. to table 1 (EN ISO 7886-2:2020, art.14.1 = EN ISO 7886-1:2018 art. 13.1 and table 1).

d/ Tightness between barrel and piston or more precisely gasket of the piston doesn't allow air and liquid leakage past the plunger stopper or seal. Small droplets between the seals are not considered failure (EN ISO 7886-2:2020, art.14.2 = EN ISO 7886-1:2018 art. 13.2 and Annex B, D).

e/ Movement of the piston in barrel is continuous and without stuttering. (EN ISO 7886-1:2018, Annex E).

f/ Syringe construction ensures syringe stability on surface with the gradient of max. 10° from the horizontal position. (EN ISO 7886-1:2018, art.10.2).

III.2. Extraneous matter (EN ISO 7886-2:2020, art. 5, 6, 7, = EN ISO 7886-1:2018 art. 6):

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.

d/ Quantity of lubricant applied to interior surface of the syringe comply with requirement of EN ISO 7886-2:2020 art.8 (id. EN ISO 7886-1:2018 art.7) not exceed 0,25 mg/cm2 of the interior surface area of the syringe in contact with the injection fluid. The amount and distribution of lubricant applied is optimized to minimize lubricant visibility.

Production takes place in clean rooms class ISO8.

III.3. Scale (EN ISO 7886-2:2020, art. 10 = EN ISO 7886-1:2018, art. 9)

a/ The basic dimensions and scale division correspond to the data in Table No. 1. (EN ISO 7886-1:2018, art. 9.1.1).

b/ In case of the extension of the scale above nominal volume, scale is separated by encircling the number of the nominal volume. (EN ISO 7886-1:2018, art.9.1.2).

c/ Lines of the scale have uniform thickness and lie perpendicular to the axis of the barrel. When the syringe is placed vertically (the cone upwards) the figures are placed on the right side from the lines of the scale and symmetrically to the respective lines. (EN ISO 7886-1:2018, art.9.1.3, 9.1.4 and 9.1.5).

d/ The length of the shorter scale lines is equal to ½ length of the longer scale lines. EN ISO 7886-1:2018, art. 9.1.5.).

III.4. Nozzle (EN ISO 7886-2:2020, art. 13)

a/ Nozzle comply with requirements EN ISO 80369-7:2017 (EN ISO 7886-2:2020, art.13.1)

b/ Diameter of nozzle opening is at least 1,2 mm. (EN ISO 7886-2:2020, art.12.3)

c/ Syringes have nozzle placed centrically.

III.5. Flow properties and flexibility of syringe (EN ISO 7886-2:2020, art. 14.3, 14.4, 14.5)

a/ The flow rates, start-up time (exclusion time) and analysis period are according to table no.2: (EN ISO 7886-2:2020, art.14.3).

Tab.no.2:

Nominal capacity of syringe V (ml)	***Flow rate (ml/h)***	***Start-up time (min)***	***Analysis period (min)***
$10 \leq V$	5	30	60 Minus parking position

b/ The maximal permissible error in flow rate deviation by measuring in two observation-time windows comply with values in the table no.3: (EN ISO 7886-2:2020, art.14.3).

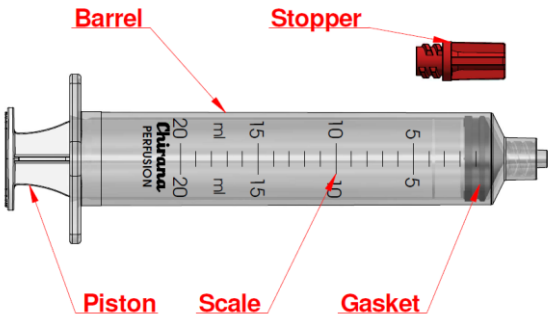
Tab.no.3:

Observation-time window (min)	***Max. error in flow rate (%)***
2	±5
5	±4

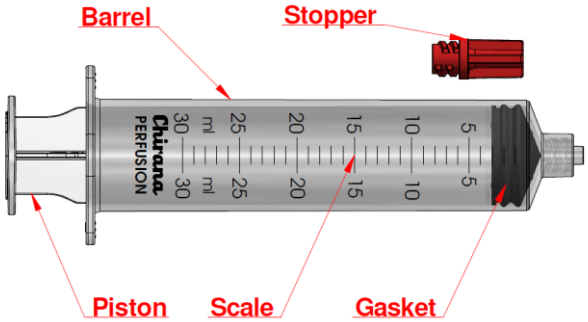
c/ The maximal amount of extruded liquid complies with requirements of EN ISO 7886-2:2020, art. 14.5.

d/ The force needed for movement piston in the barrel comply with requirements of EN ISO 7886-2:2020, art. 14.4.

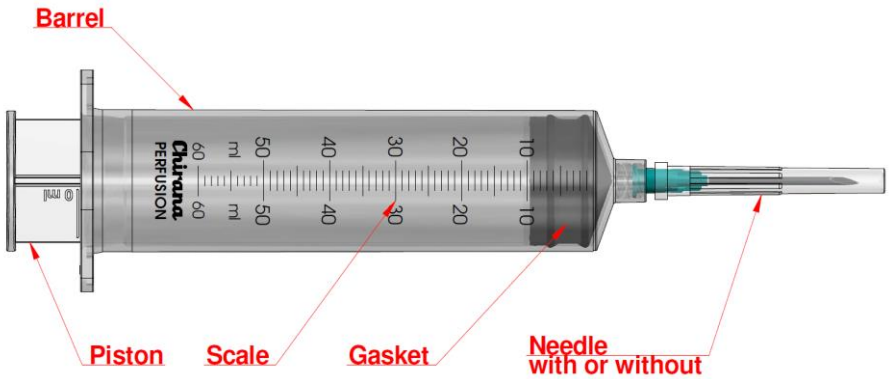
III.6. Syringe sketch



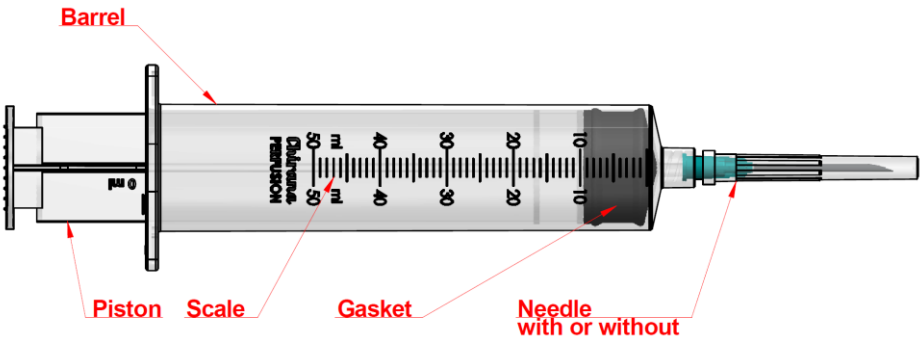
Picture. 1 – Perfusion syringe 20ml L-L



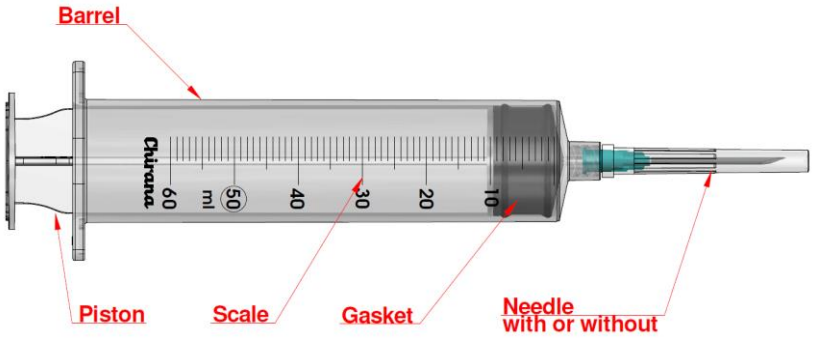
Picture. 2 – Perfusion syringe 30ml L-L



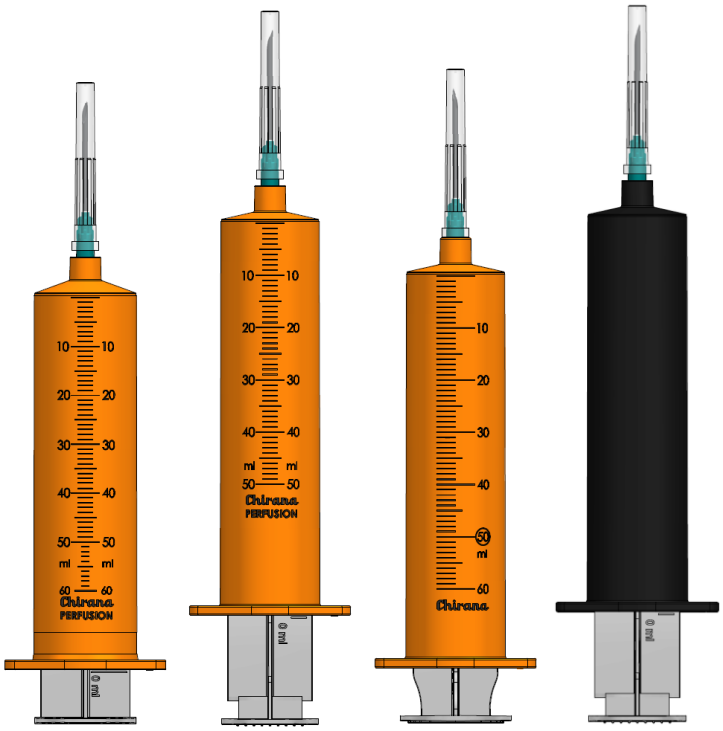
Picture. 3 - Perfusion syringe 50ml L-L, F



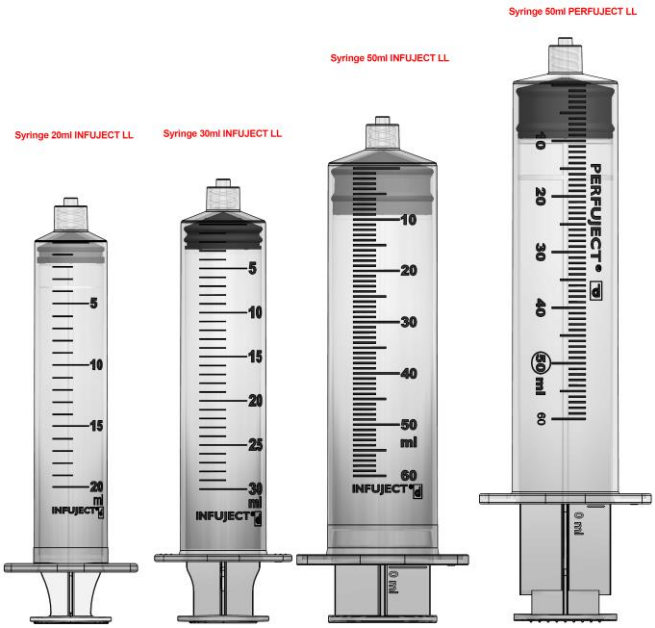
Picture. 4 - Perfusion syringe 50ml L-L, BB



Picture. 5 – Perfusion syringe 50ml L-L



Picture. 6 – Perfusion syringe 50ml – opaque / black with needle



Picture. 7 – Perfusion syringe 20, 30, 50ml – INFUJECT / PERFUJECT

III.7. Materials

Material used by production of Sterile Perfusion syringes for single use:

Part of syringe	*Type of the material*
Barrel	Polypropylene (+UV absorbent)
Piston	Polypropylene
Gasket	Synthetic rubber (LATEX FREE)
Silicone oil	Polydimethyl siloxane
Scale	Paint, paint thinner
Stopper	ABS
Needle	Polypropylene + Stainless steel

Sterile Perfusion syringes for single use are made from medical harmless materials and comply with requirements of standard EN ISO 10993-1:2020 and related biocompatibility tests acc. to product characterization.

Sterile Perfusion syringes for single use opaque / black version are made from material contain added UV absorbent and masterbatch, because of suitability for use with light sensitive substances (0% UV transmittance in wavelengths 190-400nm was observed).

III.8. Sterilization

Sterile Perfusion syringes 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).

The Sterile perfusion syringe for single use 20 ml and 30 ml INFUJECT® are sterilized by GAMA sterilization in accordance with EN ISO 11137-3:2017.

III.9. Shelf-life

The package of the Sterile Perfusion syringe 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 Perfusion syringes for single use are packed in unit package, which guarantee sterility for 5 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. Sterile Perfusion syringes for single use 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 868-5:2018 / EN 868-6:2017.

d) Materials for packages and labels:

Part of the packaging	*Material package*
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

e) Dimensions and quantities in package:

*Size / type**	*Pieces in box*	*Box dimensions (mm)*	*Pieces in shipping package*	*Shipping package dimensions (mm)*
20 ml Perfusion syringe Luer-Lock	-	-	100	399 x 201 x 201
30 ml Perfusion syringe Luer-Lock	-	-	100	399 x 201 x 201
50 ml Perfusion syringe Luer-Lock, F	-	-	100	399 x 301 x 301
50 ml Perfusion syringe Luer-Lock, BB	-	-	100	399 x 301 x 301
50 ml Perfusion syringe Luer-Lock	-	-	100	399 x 241 x 301
20 ml INFUJECT	100	381 x 236 x 192	600 (6 x 100)	599 x 404 x 511
30 ml INFUJECT	100	381 x 236 x 192	600 (6 x 100)	599 x 404 x 511
50 ml INFUJECT / PERFUJECT	50	381 x 236 x 192	300 (6 x 50)	599 x 404 x 511

*Quantity in shipping packaging and dimension of shipping packaging is valid for perfusion syringe with needle or with red stopper too.

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 inspection (SOP 4810, SOP 4812, SOP 4813)

b) Data on the packaging (SOP 4113, EN ISO 7886-1:2018, art.15)

b) Air leakage past syringe piston during aspiration (EN ISO 7886-1:2018, art.13.2, Annex. B)

c) Liquid leakage at syringe piston under compression (EN ISO 7886-1:2018, art.13.2, Annex. D)

d) Liquid leakage around the syringe piston during compression (SOP 4408)

e) Piston movement in the barrel (SOP 4408)

a) Visual control of scale (SOP 4112)

f) Power needed to control piston (EN ISO 7886-1:2018, Annex. E)

g) Adhesive tensile strength test paper - foil (weld quality of packaging unit) (SOP 4403, EN 868-5:2018)

h) Airtightness of the package (SOP 4408)

i) Penetration of printing color (SOP 4408)

j) Color scale stability test (SOP 4408)

k) Determination of flow characteristics (EN ISO 7886-2:2020, 14.3, Annex A, SOP 4407)

l) Determination of syringe flexibility / compliance ((EN ISO 7886-2:2020, 14.5, Annex C)

m) Determination of forces required to move the piston (EN ISO 7886-2:2020, 14.4, Annex. B)

n) Residual (dead space) volume test (EN ISO 7886-1:2018, 13.1, Table 1, Annex C)

o) Nominal volume test (EN ISO 7886-1:2018, Table No.1)

p) Stability test against temperature changes (SOP 4404)

q) Chemical tests (European Pharmacopoeia, EN ISO 7886-1:2018, SOP 4120)

r) Biological tests – sterility, pyrogenity, haemolysis, bioburden (EN ISO 10993-1:2020, European Pharmacopoeia, SOP 4420, SOP 4421, SOP 4424, SOP 4430)

For variants with needle are performed extra tests related for hypodermic needle acc. to TPF 330-0508-01.

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 (01-12)

VIII. TRANSPORT, STORAGE

a) The transport of the packed Sterile Perfusion syringes 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 Perfusion syringes 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 syringes. Sterile Perfusion syringes for single use can be stored in the shipping containers in up to eight layers lying on each other.