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To whom it may concern

Maximum pressure declaration


"We, manufacturing company Chirana T. Injecta, a.s. located in Nam. Dr. Schweitzera 194, 916 01 Stará Turá, Slovak Republic, hereby declare following:

The table below shows the maximum pressure values in 3 different pressure units that some of our products can withstand:

ITEM	MAXIMUM PRESSURE			standard
	[kpa]	[bar]	[psi]	
Transfusion set (Chirahem)	50	0,5	7,2	ISO 1135-4
Pressure infusion set (Chiraplust P)	200	2	29	ISO 8536-8
Gravity infusion set (Chiraplust G)	20	0,2	2,9	ISO 8536-4
Extension line (Chiraline)	200	2	29	ISO 8536-9
IV cannula STANDARD/SAFETY (Chiraflex)	2060	20,6	300	ISO 10555-1 / ISO 10555-5
3-way stopcock standard (Chiraway)	450	4,5	65	ISO 8536-10
3-way stopcock lipid resistant (Chiraway)	550	5,5	79	ISO 8536-10



Branislav Munk
Sales & Marketing Manager
CHIRANA T.Injecta, a. s.

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I. SCOPE AND APPLICATION

Product name: THREE WAY STOP COCK FOR SINGLE USE – CHIRAWAY

Intended purpose: Three way stop cock for single use is intended for administration of fluids and drugs into the human circulating system – to provide access into the peripheral vascular systems through I.V. Cannula for administration of two fluids or drugs at the same time.

Trade-mark: CHIRAWAY **abbreviation:** -

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

Compatible devices: Infusion Sets, Transfusion Sets, Extension Lines

The Three way stop cock for single use is commonly used with Infusion Sets, Transfusion Sets and Extension Lines to administrate fluids and drugs into the human circulating system. Either of these products can be easily attached on the Luer-Lock, because of connectors in accordance with EN ISO 80369-7:2021. These products are not accessories / parts of our product Three way stop cock for single use, but are available as product itself in our portfolio.


II. PRODUCT VARIANTS

- Standard
- Lipid Resistant

III. TECHNICAL DATA

III.1. General

- Color design is dark blue (standard) and light blue (lipid resistant) for Three-way stop cock for single use.
- Uniform smooth bore throughout permits maximum infusion flow and prevents turbulence as well as formation of air bubbles.
- Minimum priming volume is required for accurate drug administration, app. priming volume in Three-way stop cocks for single use with / without lipid resistance is 0,23ml.
- Three-way stop cock for single use is leak-proof up to 4.5 bars (Standard) & 5.5 bars (Lipid resistant) and can withstand the pressure applied in procedure without affecting smooth rotation of handle.
- Three-way stop cock for single use (Lipid resistant) is compatible with Lipid drugs and cytostatic drugs, contraindicated with blood.
- Rotating Luer-Lock and threaded female ports facilitates safe and secure connection to Luers of other systems.
- Arrow indication marks on the handle indicate the direction of flow.
- Transparent base of channel facilitates observation of flow.
- The flow rate of Three-way stop cocks for single use is at least 350ml / min.

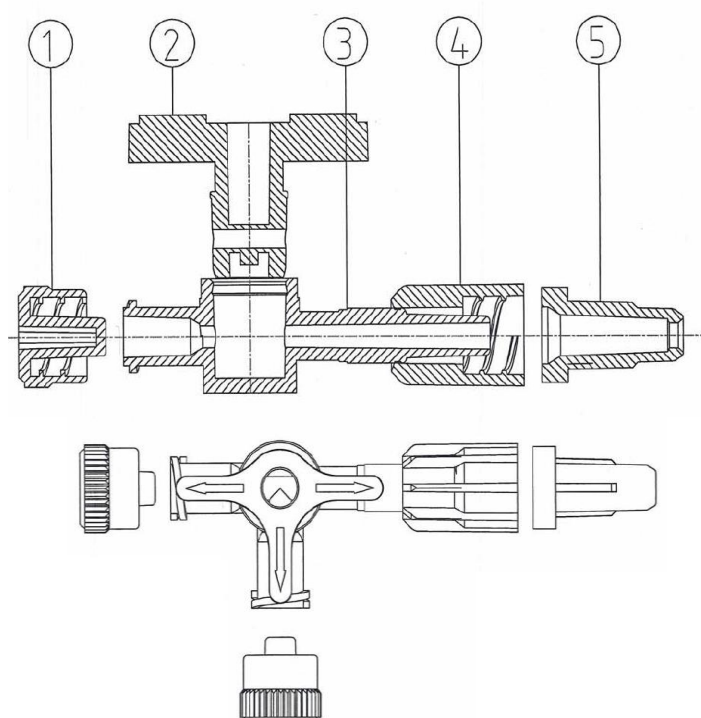
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- j/ Male or female fitting of Three-way stop cock for single use provided with 6% Luer taper for leak proof connection with other devices comply with EN ISO 80369-7:2021 (EN ISO 8536-10:2015, art. 4.5.).
- k/ Protective caps are secure but easily removable, cover the surface to prevent the contamination from environment (EN ISO 8536-10:2015, art. 4.6.).
- l/ The connection between components (between plug and housing) withstands tensile force not less 15N for 15s when in any position. (EN ISO 8536-10:2015, art. 4.3.).
- m/ There is no leakage of air or water, Three-way stop cocks for single use are tight in any plug position (EN ISO 8536-10:2015, art. 4.4.).
- n/ Three-way stop cocks for single use are designed that flow channels can be opened and closed without any adverse effect on the functionality of adjacent components (EN ISO 8536-10:2015, art. 4.7.).
- o/ The package of the Three-way stop cock for single use and its integrity ensures the sterility and usability for the period of expiration time 5 years provided the transport and storage condition according chapter VIII.

III.2. Cleanliness

- a/ Three-way stop cocks for single use are manufacture under conditions that minimize particulate contamination. The fluid pathway surfaces are smooth and clean. (EN ISO 8536-10:2015, art. 4.2.).
- b/ The production is provided in clean rooms ISO 7.

III.3. Three-way stop cock for single use design



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III.4. Materials

Material used by production of Three-way stop cock [for single use](#):

No.	Part	Type of the material
1	Luer Lock	Polyethylene (HDPE)
2	Handle	Polyethylene (HDPE)
3	Channel	Polycarbonate (PC)
4	Screw cap	Polycarbonate (PC)
5	Cock cap	Polycarbonate (PC)

Three-way stop cocks [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.

III.5. Sterilization

Three-way stop cocks [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.6. Shelf-life

The package of the Three-way stop cocks [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


Three-way stop cocks [for single use](#) 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. Three-way stop cocks [for single use](#) are afterwards packed in box and 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:

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

- Dimensions and quantities in package:

Blister (mm)	Pieces in box	Box dimensions (mm)	Pieces in shipping package	Shipping package dimensions (mm)
76x38	50	145x135x105	1 000 (20x50)	560x295x320

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V. IDENTIFICATION OF THE PRODUCT

a/ The product is identified by product name, type (product code) and lot number (LOT).

Date of the sterilization related to production date.

Lot number of the products can be defined following:

1 XXXXYM or 3 XXXXYM

where: the first one number (1 or 3) is identification number of Plot.

XXXX is the serial number of LOT

YY are the last two digits of the year

M is month of production defined by letter code acc. to the table:

<i>Month</i>	<i>Code</i>	<i>Month</i>	<i>Code</i>
January	A	July	G
February	B	August	H
March	C	September	K
April	D	October	L
May	E	November	M
June	F	December	N

For example: LOT: **1096021A**

- 1 identified Plot number of production place
- 0960 is serial number of LOT
- 21A means that production was in January 2021


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 4600)
- b/ Visual inspection of product design
- c/ Test of particulate contamination (EN ISO 8536-10:2015, Annex A.2)
- d/ Test of tensile strength (EN ISO 8536-10:2015, Annex A.3)
- e/ Test of connectors leakage (EN ISO 8536-10:2015, Annex A.4)
- f/ Test of conical fitting and flow rate (EN ISO 80369-7:2017)
- g/ Chemical tests (EN ISO 8536-10:2015, Annex B)
- h/ Biological tests biocompatibility (EN ISO 8536-10:2015, Annex C, EN ISO 10993-1:2020)
- i/ Bacterial endotoxins test (EuPh 2.6.14)
- j/ Sterility test (EuPh 2.6.1)

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VII. DELIVERY, GUARANTEE

- 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 Three-way stop cocks **for single use** can be carried out only in covered, clean and dry means of transport at the temperature between +5°C to +35°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) Three-way stop cocks **for single use** must be stored in dry, ventilated, dust-free, dark rooms at the temperature within the range from +5°C to +35°C. No organic solvents and chemicals are allowed to be stored with the Three-way stop cocks **for single use**.