

	Product specification	PS 310-0918-06	Revision: 2.0
	STOPPER FOR SINGLE USE - CHIRAPLUS		Valid from: 16.08.2022 Page: 1/3

SECTION I: PRODUCT DESCRIPTION

- 1.1 Product name: **Stopper for single use (Combistopper)**
- 1.2 Trade mark: **CHIRAPLUS**
- 1.3 Product type: sterile, for single use
- 1.4 Intended purpose: Stopper for single use is intended for closure of Luer Lock connectors.
- 1.5 Product classification: based on MDR 2017/745, Annex VIII as Class IIa, Rule 2
- 1.6 Compatible devices: Medical devices with connector according to EN ISO 80369-7:2021. (e.g., I.V. Cannula)
The Stopper is used to close a medical device so nothing will flow out from the medical device and neither will foreign matter be able to enter into the medical device and possibly into patients' body. These products are not accessories / parts of our product Stopper for single use, but are available as product itself in our portfolio.
- 1.7 Technical data:
- Material: Combistopper - PE (Polyethylene)
Stopper for single use is made from medically harmless material.
- 1.8 Design:



- 1.9 Sterilization: Stoppers for single use are sterilized by ethylene oxide in its final package using validate sterilization process (EN ISO 11135:2014) insuring SAL at least 10^{-6} (EN 556-1:2001).
- 1.10 Production: Production takes place in clean rooms class ISO 8 according to EN ISO 14644-1:2015.

SECTION II: PERFORMANCE SPECIFICATION

2.1 Packaging:

Product	REF code CHIRANA	Blister dimensions (mm)	Pieces in Box	Box dimensions (mm)	Pieces in carton	Carton dimensions (mm)
Combistopper for single use (red)	CHCS01	68 x 38	100	170 x 135 x 105	2 000 (20 x 100)	545 x 295 x 350
Combistopper for single use (blue)	CHCS02					
Combistopper for single use (white)	CHCS03					

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SECTION III: PRODUCT IDENTIFICATION

3.1 Identification of product (LOT):

The product is identified by product name, type (product code) and lot number (LOT). Lot number of the products and production date can be defined following:

1XXXXYYM or **3XXXXYYM**

where: first number 1 or 3 is identification number of production line

XXXX is serial number of LOT

YY last number of year

M is month of production form 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

3.2 Date of production in this format: **YYYY-MM**

where: YYYY is year of production

MM is month of production (01-12)

SECTION IV: TRANSPORT AND STORAGE

4.1 Transport condition:

The transport of the packed product can be carried out only in covered, clean and dry means of transport at the temperature +5°C - +35°C. Take care of warning data marked on the package during the transport.

4.2 Storage conditions:

The product should be stored in dry, ventilated, dust-free rooms which are protected from the straight effect of the solar radiation at the temperature +5°C - +35°C. No organic solvents and chemicals are allowed to be stored with them.

SECTION V: DELIVERY, GUARANTEE

5.1 Certificate of quality:

With each delivery it is possible (according to customer requirement) to issue Certificate of quality.

Deliveries are inspected after agreement with the customer by statistical acceptance according to ISO 2859-1:1999.

5.2 Shelf-life:

The manufacturer grants the guarantee for the period of usability of the product for 5 years since the production date, provided the prescribed storage and transport conditions according to point IV.

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)

SECTION VI: RELATED STANDARDS

[MDR 2017/745](#)

EN ISO 13485:2016

[EN ISO 14971:2019](#)

[EN ISO 80369-7:2021](#)

EN ISO 11135:2014

EN ISO 14644-1:2015

[EN ISO 15223-1:2021](#)

[EN ISO 11607-1:2020](#)

ISO 2859-1:1999

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