	Technical data sheet	Attachment no. 6 pt. 1 subpt. 1.1
	TD-41 dicoNEX	Edition II 2019.02.27
	Single use syringe, 3-part	Page 1/2

MEDICAL DEVICE DATA:			
CATALOGUE NUMBER	020ML-3CZ-BL 020ML-3CZ-LL-BL		
MANUFACTURER	ZARYS International Group sp. z o.o. sp.k., Poland		
CLASSIFICATION	II a	RULE	2
METHOD OF STERILIZATION	Ethylene oxide	CODE OF GENERIC DEVICE GROUP ACCORDING TO GMDN	47017
PERFORMANCE CHARACTERISTICS	<ul style="list-style-type: none"> <li>▪ 3-part syringe for intramuscular, intravenous and subcutaneous injection</li> <li>▪ Intended for administering drugs / liquids / food to the patient. It can also be used to take body fluid samples from the patient</li> </ul>		
CURRENT TECHNICAL STANDARDS ARE APPLICABLE TO THE DEVICE	ISO 7886-1 Sterile hypodermic syringes for single use		

TECHNICAL DATA:	
RAW MATERIALS	<ol style="list-style-type: none"> <li>1. barrel – polypropylene</li> <li>2. plunger/piston – polypropylene</li> <li>3. rubber sealing – polyisoprene rubber (synthetic)</li> <li>4. silicone oil (polysiloxane)</li> </ol>
COLOUR	<ol style="list-style-type: none"> <li>1. barrel – transparent</li> <li>2. plunger/piston – green</li> <li>3. rubber sealing – black</li> <li>4. silicone oil – transparent</li> </ol>
FEATURES	<ul style="list-style-type: none"> <li>▪ three-piece syringe</li> <li>▪ transparent barrel allows perfect visualization of the content</li> <li>▪ green contrasting plunger</li> <li>▪ luer or luer-lock nozzle with dead space 0,035 ml</li> <li>▪ sealing in the form of a double ring on a plunger stopper situated on the top of plunger</li> <li>▪ smooth plunger movement thanks to rubber sealing and silicone oil on the inner surface of the barrel</li> <li>▪ limitation flange securing against accidental removal of the plunger</li> <li>▪ name of the syringe and manufacturer's logo placed on the barrel</li> <li>▪ clear, legible and permanent black graduation facilitating dosing ever 0,5ml</li> <li>▪ single-use, non-pyrogenic, non-toxic</li> <li>▪ latex-free</li> <li>▪ phthalate-free</li> <li>▪ EO sterilized</li> <li>▪ shelf life: 5 years</li> </ul>
VARIABLES	020ML-3CZ-BL with luer nozzle 020ML-3CZ-LL-BL with luer-lock nozzle
SIZE/CAPACITY	20 ml

**TECHNICAL DRAWING**

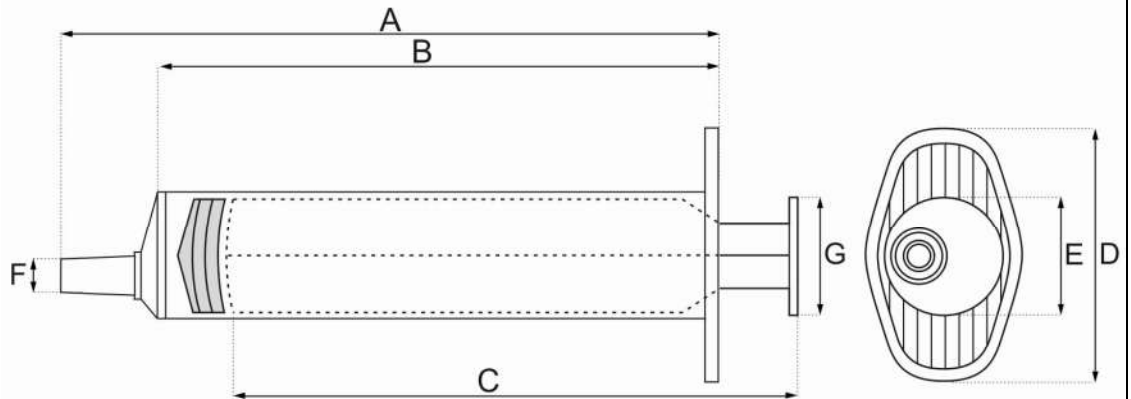


Fig. 1 Syringe 020ML-3CZ-BL

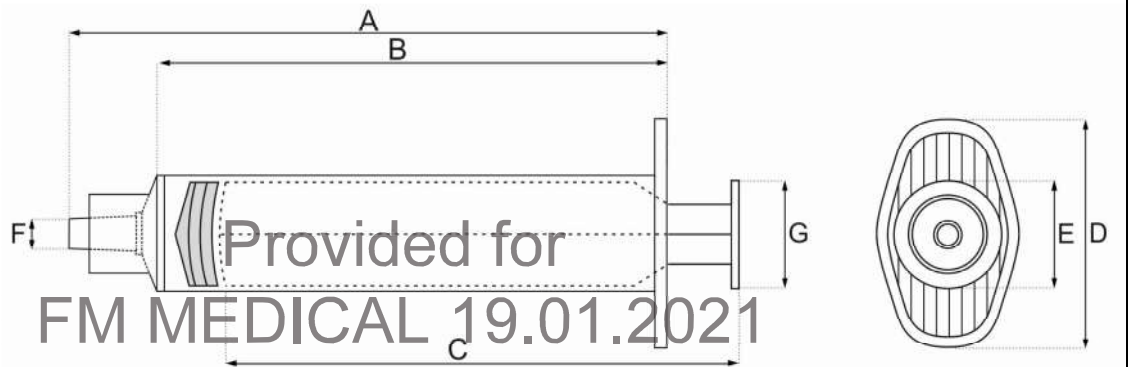


Fig. 2 Syringe 020ML-3CZ-LL-BL

**DESCRIPTION OF PARTS OF THE PRODUCT AND ITS FUNCTION**

- barrel – a graduated container with a luer/luer-lock nozzle
- clear, legible and permanent black graduation every 0,5 ml to facilitate precise dosing
- plunger/piston – integral construction with a push-bottom. Allows the piston to be moved along the entire length of the barrel
- rubber sealing – ensures smooth piston movement along the entire length of the barrel and guarantees tightness of the syringe
- silicone oil – covers the inner surface of the barrel allowing a smooth movement of the sealing rubber

**DETAILED DIMENSIONS / SPECIFICATION**

REF	dimension	A	B	C	D	E (I.D.)	F (I.D.)	G
020ML-3CZ-BL		105,0 mm	94,4 mm	100,6 mm	36,5 mm	Ø 19,2 mm	Ø 2,5 mm	Ø 20,6 mm
020ML-3CZ-LL-BL		104,5 mm	94,4 mm	100,6 mm	36,5 mm	Ø 19,2 mm	Ø 2,5 mm	Ø 20,6 mm
	size tolerance	± 0,4 mm	± 0,4 mm	± 0,5 mm	± 0,3 mm	± 0,08 mm	-	± 0,2 mm

**PACKAGING**

type of packaging	number of pieces	packaging material	packaging size [mm]
individual	1 pc.	paper/foil	169 x 56
intermediate	50 pcs	mixed paper	235 x 150 x 180
bulk	16 x 50 pcs	corrugated cardboard	615 x 470 x 340

**STORAGE CONDITIONS**

temperature:	-5°C – 40°C
humidity:	30% – 80%