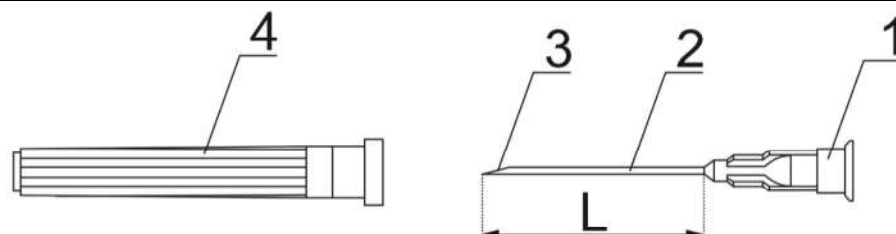


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MEDICAL DEVICE DATA:			
CATALOGUE NUMBER	IN-YYxYY; DW IN-YYxYY		
MANUFACTURER	ZARYS International Group sp. z o.o. sp.k., Poland		
CLASSIFICATION	Ila	RULE	6
METHOD OF STERILIZATION	Ethylene oxide	CODE OF GENERIC DEVICE GROUP ACCORDING TO GMDN	20212
PERFORMANCE CHARACTERISTICS	Device is intended for intravenous, intramuscular and subcutaneous injection in connection with infusion / transfusion sets or disposable syringes		
CURRENT TECHNICAL STANDARDS ARE APPLICABLE TO THE DEVICE	EN ISO 7864 Sterile hypodermic needles for single use — Requirements and test methods EN ISO 6009 Hypodermic needles for single use — Colour coding for identification EN ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods EN ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications		

TECHNICAL DATA:	
RAW MATERIALS	▪ needle tube – stainless steel ▪ hub – PP ▪ sheath – HDPE ▪ connecting the needle with the hub – epoxy resin
COLOUR	▪ needle – steel ▪ hub – needle size colour coding ▪ sheath – transparent
FEATURES	• needle with good stiffness and strength with a pointed tip to reduce patient pain • needle tube covered with a lubricant – medical silicone oil • blade cut at an angle ($11 \pm 2^\circ$) • tip sharpened in three surfaces • bevel type: LB/BL standard long bevel • glued needle elements to prevent their separation (glue – epoxy resin) • hermetic sheath provides adequate needle protection • flow rate less than 5% • available in different sizes – hub colour coding • single-use • non-toxic, non-pyrogenic • phthalate-free • latex-free • for temporary use • EO sterilized • shelf life – 5 lat
SIZES	0.30 – (30G), 0.40 – (27G), 0.45 – (26G), 0.50 – (25G), 0.60 – (23G), 0.70 – (22G), 0.80 – (21G), 0.90 – (20G), 1.10 – (19G), 1.20 – (18G), 1.60 – (16G), 1.80 – (15G), 2.10 – (14G)

TECHNICAL DRAWING



DESCRIPTION OF PARTS OF THE PRODUCT AND ITS FUNCTION

1. hub – allows the needle to be connected to the syringe cone
2. needle tube – transports the drug from the hub to the puncture site
3. blade – punctures skin, tissue and muscles by inserting the needle tube into the desired puncture site
4. sheath – protects the needle from contamination and damage

DETAILED DIMENSIONS / SPECIFICATION

REF		L - needle tube length [mm]	needle tube length tolerance	outer diameter (OD) / inner (ID) of the needle tube [mm]	hub colour
IN-03X12	DW IN-03X12	12	-2 +1	0,3 / 0,133	yellow
IN-03X13	DW IN-03X13	13	-2 +1	0,3 / 0,133	yellow
IN-04X19	DW IN-04X19	19	-2 +1	0,4 / 0,184	medium grey
IN-045X12	DW IN-045X12	12	-2 +1	0,45 / 0,232	brown
IN-045X16	DW IN-045X16	16	-2 +1	0,45 / 0,232	brown
IN-045X22	DW IN-045X22	22	-2 +1	0,45 / 0,232	brown
IN-05X16	DW IN-05X16	16	-2 +1	0,5 / 0,232	orange
IN-05X20	DW IN-05X20	20	-2 +1	0,5 / 0,232	orange
IN-05X25	DW IN-05X25	25	-2,5 +1,5	0,5 / 0,232	orange
IN-05X40	DW IN-05X40	40	-4	0,5 / 0,232	orange
IN-06X25	DW IN-06X25	25	-2,5 +1,5	0,6 / 0,37	deep blue
IN-06X30	DW IN-06X30	30	-2,5 +1,5	0,6 / 0,37	deep blue
IN-06X40	DW IN-06X40	40	-4	0,6 / 0,37	deep blue
IN-07X30	DW IN-07X30	30	-2,5 +1,5	0,7 / 0,44	black
IN-07X40	DW IN-07X40	40	-4	0,7 / 0,44	black
IN-07X50	DW IN-07X50	50	-2,5 +1,5	0,7 / 0,44	black
IN-08X25	DW IN-08X25	35	-2,5 +1,5	0,8 / 0,547	deep green
IN-08X40	DW IN-08X40	40	-4	0,8 / 0,547	deep green
IN-08X50	DW IN-08X50	50	-2,5 +1,5	0,8 / 0,547	deep green
IN-09X25	DW IN-09X25	25	-2,5 +1,5	0,9 / 0,635	yellow
IN-09X40	DW IN-09X40	40	-4	0,9 / 0,635	yellow
IN-11X40	DW IN-11X40	40	-4	1,1 / 0,75	cream
IN-12X40	DW IN-12X40	40	-4	1,2 / 0,91	pink
IN-12X50	DW IN-12X50	50	-2,5 +1,5	1,2 / 0,91	pink
IN-16X40	DW IN-16X40	40	-4	1,6 / 1,283	white
IN-18X40	DW IN-18X40	40	-4	1,8 / 1,46	blue-grey
IN-21X40	DW IN-21X40	40	-4	2,1 / 1,6	pale green

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PACKAGING	type of packaging	number of pieces	packaging size [mm]	packaging material
	individual	1	80x20	paper/foil
	intermediate	100	95x85x90	flat cardboard
	bulk	50 x 100	475x450x215	corrugated cardboard
STORAGE CONDITIONS	temperature:	5°C - 40°C		
	humidity:	30%-80%		

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