



# Technical data sheet

Attachment no. 6  
pt. 1 subpt. 1.1

TD-42  
dispoFINE Injection needle  
docFINE Injection needle

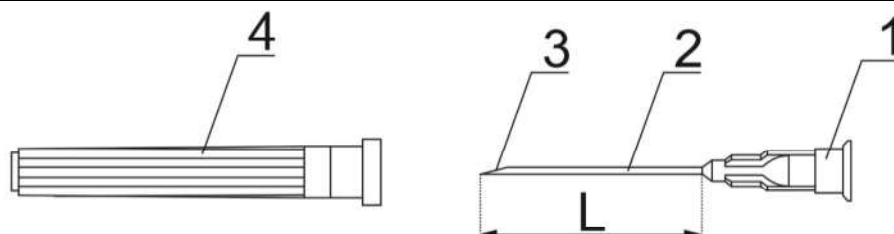
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MEDICAL DEVICE DATA:			
CATALOGUE NUMBER	IN-YYxYY; DW IN-YYxYY		
MANUFACTURER	ZARYS International Group sp. z o.o. sp.k., Poland		
CLASSIFICATION	Ila	RULE	6
METHOD OF STERILIZATION	Ethylene oxide	CODE OF GENERIC DEVICE GROUP ACCORDING TO GMDN	20212
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	<ul style="list-style-type: none"> <li>▪ needle tube – stainless steel</li> <li>▪ hub – PP</li> <li>▪ sheath – HDPE</li> <li>▪ connecting the needle with the hub - epoxy resin</li> </ul>
COLOUR	<ul style="list-style-type: none"> <li>▪ needle – steel</li> <li>▪ hub – needle size colour coding</li> <li>▪ sheath - transparent</li> </ul>
FEATURES	<ul style="list-style-type: none"> <li>• needle with good stiffness and strength with a pointed tip to reduce patient pain</li> <li>• needle tube covered with a lubricant - medical silicone oil</li> <li>• blade cut at an angle (<math>11 \pm 2^\circ</math>)</li> <li>• tip sharpened in three surfaces</li> <li>• bevel type: LB/BL standard long bevel</li> <li>• glued needle elements to prevent their separation (glue - epoxy resin)</li> <li>• hermetic sheath provides adequate needle protection</li> <li>• flow rate less than 5%</li> <li>• available in different sizes - hub colour coding</li> <li>• single-use</li> <li>• non-toxic, non-pyrogenic</li> <li>• phthalate-free</li> <li>• latex-free</li> <li>• for temporary use</li> <li>• EO sterilized</li> <li>• shelf life – 5 lat</li> </ul>
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%		

Provided for  
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