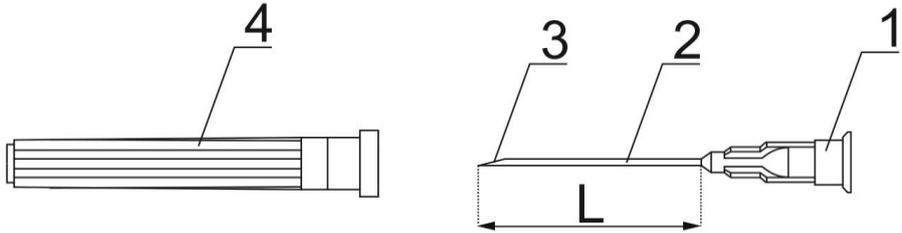


	Technical data sheet	Attachment no. 6 pt. 1 subpt. 1.1
	TD-42 dispoFINE Injection needle docFINE Injection needle	Edition II 2020.02.21
		Page 1/2

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	<ol style="list-style-type: none"> <li>1. hub – allows the needle to be connected to the syringe cone</li> <li>2. needle tube – transports the drug from the hub to the puncture site</li> </ol>



# Technical data sheet

Attachment no. 6  
pt. 1 subpt. 1.1

TD-42  
dispoFINE Injection needle  
docFINE Injection needle

Edition II  
2020.02.21

Page 2/2

<b>PRODUCT AND ITS FUNCTION</b>	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						
<b>DETAILED DIMENSIONS / SPECIFICATION</b>	REF		L - needle tube length [mm]	needle tube length tolerance	outer diameter (OD) / inner (ID) of the needle tube [mm]	dead space [mm]	hub colour
	IN-03X12	DW IN-03X12	12	-2 +1	0,3 / 0,133	~0,1144	yellow
	IN-03X13	DW IN-03X13	13	-2 +1	0,3 / 0,133	~0,1149	yellow
	IN-04X19	DW IN-04X19	19	-2 +1	0,4 / 0,184	~0,1184	medium grey
	IN-045X12	DW IN-045X12	12	-2 +1	0,45 / 0,232	~0,1179	brown
	IN-045X16	DW IN-045X16	16	-2 +1	0,45 / 0,232	~0,1186	brown
	IN-045X22	DW IN-045X22	22	-2 +1	0,45 / 0,232	~0,1214	brown
	IN-05X16	DW IN-05X16	16	-2 +1	0,5 / 0,232	~0,1190	orange
	IN-05X20	DW IN-05X20	20	-2 +1	0,5 / 0,232	~0,1216	orange
	IN-05X25	DW IN-05X25	25	-2,5 +1,5	0,5 / 0,232	~0,1227	orange
	IN-05X40	DW IN-05X40	40	-4	0,5 / 0,232	~0,1287	orange
	IN-06X25	DW IN-06X25	25	-2,5 +1,5	0,6 / 0,37	~0,1237	deep blue
	IN-06X30	DW IN-06X30	30	-2,5 +1,5	0,6 / 0,37	~0,1243	deep blue
	IN-06X40	DW IN-06X40	40	-4	0,6 / 0,37	~0,1264	deep blue
	IN-07X30	DW IN-07X30	30	-2,5 +1,5	0,7 / 0,44	~0,1282	black
	IN-07X40	DW IN-07X40	40	-4	0,7 / 0,44	~0,1298	black
	IN-07X50	DW IN-07X50	50	-2,5 +1,5	0,7 / 0,44	~0,1310	black
	IN-08X25	DW IN-08X25	35	-2,5 +1,5	0,8 / 0,547	~0,1295	deep green
	IN-08X40	DW IN-08X40	40	-4	0,8 / 0,547	~0,1318	deep green
	IN-08X50	DW IN-08X50	50	-2,5 +1,5	0,8 / 0,547	~0,1349	deep green
	IN-09X25	DW IN-09X25	25	-2,5 +1,5	0,9 / 0,635	~0,1306	yellow
	IN-09X40	DW IN-09X40	40	-4	0,9 / 0,635	~0,1350	yellow
	IN-11X40	DW IN-11X40	40	-4	1,1 / 0,75	~0,1444	cream
	IN-12X40	DW IN-12X40	40	-4	1,2 / 0,91	~0,1555	pink
IN-12X50	DW IN-12X50	50	-2,5 +1,5	1,2 / 0,91	~0,1612	pink	
IN-16X40	DW IN-16X40	40	-4	1,6 / 1,283	~0,1798	white	
IN-18X40	DW IN-18X40	40	-4	1,8 / 1,46	~0,1877	blue-grey	
IN-21X40	DW IN-21X40	40	-4	2,1 / 1,6	~0,2013	pale green	
<b>PACKAGING</b>	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
<b>STORAGE CONDITIONS</b>	temperature:		5°C - 40°C				
	humidity:		30%-80%				