

Material Description: Sterile, Single-Use, Hypodermic Needle

Regulatory Requirements: ISO 13485 – Medical Devices
ISO 7864 – Sterile hypodermic needles for single use

Materials of Construction:

- Needle cannula – Stainless Steel according to ISO 9626
- Needle hub – Polypropylene per ISO 80369-7, ISO 594-2; Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
- Protective Cap – Polypropylene
- Siliconization according to ISO 7864: Undiluted polydimethylsiloxane, maximum 0.25 mg/cm² on surface of needle

Physical Qualities:

- Wall Diameters according to ISO 9626

<u>Gauge</u>	<u>OD min (mm)</u>	<u>OD max (mm)</u>	<u>Wall Type</u>	<u>ID min (mm)</u>
30	0.298	0.320	RW	0.133
27	0.400	0.470	RW	0.184
25	0.500	0.530	TW	0.292
23	0.600	0.673	TW	0.370
22	0.698	0.730	TW	0.440
21	0.800	0.830	TW	0.547
20	0.860	0.920	TW	0.635
19	1.030	1.100	TW	0.750
18	1.200	1.300	TW	0.910

- Grinding Angles according to ISO 7864:
 - 18g and 19g – Short Bevel 17° +/- 2°
 - 20g to 30g – Long Bevel 11° +/- 2°
- Needle Tolerances according to ISO 7864:
 - < 25mm: +1mm / -2mm
 - 25mm – 39mm +1.5mm / -2.5mm
 - 40mm 0 / -4mm
 - >40mm +1.5mm / -2.5mm
- Connecting Strength between needle hub and cannula according to ISO 7864.
- Shelf Life for Sterile Product 5 years

Chemical Qualities:

- Limits for acidity, alkalinity, and extractable metals per ISO 7864

Biological Qualities:

- Needle according to ISO 10993-1:
 - Haemolysis (ISO 10993-4)
 - Cytotoxicity (ISO 10993-5)
 - Systemic Toxicity (ISO 10993-11)
- Non-pyrogenic
 - All batches / lots less than 2.15 EU / needle
- Latex free
- Free of PVC plasticizers and phthalates
- Bisphenol-A free
- REACH 1907/2006 – Does not contain any substances outlined in the SVHC list
- BSE / TSE – Does not contain any animal sources
- Sterilization with Ethylene Oxide (EtO) according to:
 - ISO 11135 – Medical Devices – Validation and routing control of ethylene oxide sterilization
 - Residual gas analysis according to ISO 10993-7

Packaging:

- Primary container according to ISO 11607-1 – Heat sealed peel-off blister package consisting of composite PP/PE film backed by medical grade paper
- ½" to 1-1/2" needles:
 - Inner box = 100 pieces
 - Inner case = 2,000 pieces
 - Outer case = 10,000 pieces
- 2" needles:
 - Inner box = 100 pieces
 - Inner case = 2,000 pieces
 - Outer case = 8,000 pieces
- 3" and 4" needles:
 - Inner box = 100 pieces
 - Outer case = 2,000 pieces

Intended Use:

The single-use hypodermic needles are used for intravenous, intramuscular, subcutaneous, intracutaneous, and intraarterial injection of liquids or diluted drugs in combination with adequate medical device or for withdrawal of fluids from the body or vial.



PRODUCT SPECIFICATION

PRODUCT: EZ FLO NEEDLES

Revision Date Nov 2022

GUDID Reference:

<u>ProdCode</u>	<u>BOX</u>	<u>CASE</u>	<u>MASTER CASE</u>	<u>Unit of Use</u>
NEZ18100	10850017403045	20850017403042	30850017403049	00850017403048
NEZ18112	10850017403052	20850017403059	30850017403056	00850017403055
NEZ18200	10850017403069	20850017403066	30850017403063	00850017403062
NEZ19100	10850017403076	20850017403073	30850017403070	00850017403079
NEZ19112	10850017403083	20850017403080	30850017403087	00850017403086
NEZ20100	10850017403090	20850017403097	30850017403094	00850017403093
NEZ20112	10850017403106	20850017403103	30850017403100	00850017403109
NEZ21100	10850017403113	20850017403110	30850017403117	00850017403116
NEZ21112	10850017403120	20850017403127	30850017403124	00850017403123
NEZ21200	10850017403137	20850017403134	30850017403131	00850017403130
NEZ22034	10850017403144	20850017403141	30850017403148	00850017403147
NEZ22100	10850017403151	20850017403158	30850017403155	00850017403154
NEZ22112	10850017403175	20850017403172	30850017403179	00850017403161
NEZ22200	10850017403168	20850017403165	30850017403162	00850017403161
NEZ22300	10850017403182	20850017403189	x	00850017403185
NEZ22400	10850017403199	20850017403196	x	00850017403192
NEZ23034	10850017403205	20850017403202	30850017403209	00850017403208
NEZ23100	10850017403212	20850017403219	30850017403216	00850017403215
NEZ23112	10850017403229	20850017403226	30850017403223	00850017403222
NEZ25058	10850017403236	20850017403233	30850017403230	00850017403239
NEZ25100	10850017403243	20850017403240	30850017403247	00850017403246
NEZ25112	10850017403250	20850017403257	30850017403254	00850017403253
NEZ25200	10850017403267	20850017403264	30850017403261	00850017403260
NEZ27100	10850017403274	20850017403271	30850017403278	00850017403277
NEZ27112	10850017403281	20850017403288	30850017403285	00850017403284
NEZ27114	10850017403298	20850017403295	30850017403292	00850017403291
NEZ27200	10850017403304	20850017403301	30850017403308	00850017403307
NEZ30012	10850017403311	20850017403318	30850017403315	00850017403314
NEZ30100	10850017403328	20850017403325	30850017403322	00850017403321