

EC DECLARATION OF CONFORMITY

BERİKA TEKNOLOJİ MEDİKAL İMALAT İTHALAT İHRACAT TİCARET LTD. ŞTİ.

Address : Alakova Mahallesi Karaman Caddesi No:812 MERAM-KONYA-TÜRKİYE

Tel : +903322389998

Fax : +903322379981

E-mail : office@berikamedikal.com.tr

Product Name: Syringes-Hypodermic-One-use sterile compartment 1: Syringes-For hand use (1ml, 2ml, 3ml, 5ml, 10ml, 20ml and 50ml disposable sterile syringe with / without needle (product list is attached)

Classification: Class IIA, Rule 6 ANNEX IX

Conformity assessment path: Annex V

GMDN NO: 47017

47017-General purpose syringe DESCRIPTION: A general medical purpose sterile device consisting of a calibrated empty chamber (cylinder) and a movable piston, to inject or draw liquids / gases from the body or a medical device. At the distal end of the barrel there is a male connector (typically Luer type lock) for inserting the hypodermic needle or female connector (hub) of the administration set. It is typically made of plastic and silicone material, and the piston may have anti-adhesive properties (pre-coated with suitable materials) to ensure smooth movement of the piston, either by hand or by the syringe pump. It is a single use device. CATEGORIES: 10. Disposable devices TYPE: APPLICABLE TERM

We declare that the aforementioned product is class IIA sterile according to the Medical Devices Directive 93/42 EEC and 2007/47 EC Medical Devices Regulation in terms of safety and health requirements.

General applicable regulations and standards

Medical Devices Regulation: 14 June 1993 Council Regulation 93/42 EEC and 2007/47 / EC Regulation on medical devices, TS EN ISO 13485 Medical devices quality management system, all relevant harmonized standards are included.

Notified Body : Udem Uluslararası Belgelendirme Denetim Eğitim
Merkezi Sanayi ve Ticaret Limited Şirketi
Notified Body Address : Mutlukent Mah. 2073 Sk. No:10 Ümitköy - Çankaya ANKARA
Telephone : +90.312.443 03 90(pbx)
Notified Body Number : 2292
Cert. No : M.2016.106.6915
Starting Lot number : xxx
Place, Release Date :KONYA, 05.08.2016
Revision Date / Revision no :24.02.2020/01
Document Validity Date :27.05.2024

Annex1: Product List

Annex2: TD-01 Section 4

General Manager:HAYRETTİN ŞEKER
Signature Date/ Place: 24.02.2020/KONYA

Stamp – Signature

BERİKA TEKNOLOJİ MEDİKAL
İmalat ve Ticaret Limited Şirketi
Alakova Mahallesi Karaman Caddesi No:812 Meram/KONYA
Tel: 0332 237 99 81 Fax: 0332 237 99 81
E-mail: office@berikamedikal.com.tr Sic. No: 27415 Gıda Sic. No: 51904
www.berikamedikal.com.tr

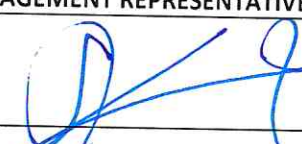



Technical DOSYA TD-01

Syringes-Hypodermic -One-use sterile section 1: Syringes-
For manual use
(3-PACK SINGLE USE SHOW NEEDLE/NEEDLE FREE 1,2-
2,5,3,5,10,20 and 50 ml Syringes and SINGLE-USE SHOW
HYPODIC NEEDLE)

PART NAME	APPLIED STANDS AND REGULATIONS
PART NO.	4

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30.05.2016	11	23.12.2020	3 / 5

HAZIRLAYAN MANAGEMENT REPRESENTATIVE	Approver GENERAL MANAGER
	

TS EN ISO 14644-9 Acceptance Date: 12.06.2013	Clean rooms and related controlled environments - Part 9: Classification of surface cleaning with particle compilation
TS EN ISO 14644-14 Acceptance Date: 9.12.2016	Clean rooms and connected controlled environments – Part 14: Assessing suitability for the use of equipment with a grain-in-the- air compile
TS EN ISO 14698-1 Acceptance Date: 28.01.2004	Clean rooms and controlled environments together - Biocontamination control - Part 1: General principles and methods
TS EN ISO 10993-1 Acceptance Date: 29.03.2011	Biological Evaluation of medical instruments - Part 1: Evaluation and experiment in a risk management process (ISO 10993-1:2009)
TS EN ISO 10993-4 Acceptance Date: 19.03.2020	Biological evaluation of medical devices - Part 4: Selection of blood interaction experiments
TS EN ISO 10993-5 Acceptance Date: 13.07.2010	Biological evaluation of medical devices - part 5: Out-of-body cytotoxicity experiments
TS EN ISO 10993-7 Acceptance Date: 19.01.2010	Biological evaluation of medical devices - Part 7: Remnants of ethylene oxide sterilization (ISO 10993-7:2008)
TS EN ISO 10993-7/AC Acceptance Date: 23.03.2010	Biological evaluation of medical equipment-Part 7: Remnants of sterilization with ethylene oxide
TS EN ISO 10993-10 Acceptance Date: 13.02.2014	Biological evaluation of medical devices - Part 10: Experiments for irritation and skin sensitivity (ISO 10993-10:2010)



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TS EN ISO 10993-11 Acceptance Date: 19.11.2018	Biological evaluation of medical devices - part 11: Systemic toxicity experiments
TS EN ISO 11135 Acceptance Date: 30.10.2014	Sterilization of health supplies - Ethylene oxide - Needs for the development, validation and routine control of the sterilization process of medical devices
TS EN ISO 11607-1 Acceptance Date: 9.11.2020	Packaging for ultimately sterilized medical devices - Part 1: Rules for materials, sterile barrier systems and packaging systems
TS EN ISO 11607-2 Acceptance Date: 9.11.2020	Packaging of medical devices - Finally sterilized - part 2: Conditions of validation for formatting, sealing and joining processes
93/42/EEC Release Date: 07.06.2011	MEDICAL REGULATIONS
MEDDEV 2.12-1 rev 8 January/2013	REV.8 VIGILANCE
With. DEV.2.7.1 REV.4 June/2016	GUIDELINES ON MEDICAL DEVICES CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
With. DEV.2 4/1 REV.9 June/2010	MEDICAL DEVICES: Guidance document Classification of medical devices
2007/47/EC	MEDICAL REGULATION TEAM



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MEDDEV 2.2.3 rev.3 June/1998	GUIDELINES RELATING TO THE APPLICATION OF : THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES
"CE" SIGN REGULATION February 23rd, 2012	"CE" SIGN REGULATION
TS 3856 Acceptance Date: 21.12.1982	Analysis of harmful residues in rubber material used in the field of health
TS EN ISO 10993-18 Acceptance Date: 24.06.2010	Biological evaluation of medical devices - part 18: Determination of chemical properties of materials
MEDDEV 2. 2/1 Rev1 February/1998	GUIDELINES RELATING TO THE APPLICATION OF : THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES
EP 8.3 January/2015	European Pharmacopoeia 8.3

BERİKA TEKNOLOJİ MEDİKAL
İstanbul, Türkiye Tic. Ltd. Şti.
Kurtuluş Bulvarı No: 812, Kat: 11
Etiler, Beşiktaş, İstanbul / Türkiye
Tel: +90 212 257 59 01
Fax: +90 212 257 59 02



PRODUCT LIST

PRODUCT CODE (REF)	PRODUCT NAME	BARCODE	RAW MATERIALS	NEEDLE COLOR	GMDN CODE	INNER BOX DIMENSIONS	INNER BOX PIECES	EXTERIOR BOX DIMENSIONS	OUTER BOX PIECE	SHELF LIFE
447355	Pink 18Gx1 1/2 1.20x16 mm needle	8680075447355	Rusting Steel	pink	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
448666	Pink 18Gx1 1/2 1.20x25 mm needle	8680075448666	Rusting Steel	pink	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
449388	Pink 18Gx1 1/2 1.20x38 mm needle	8680075449388	Rusting Steel	pink	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
449571	Yellow 20Gx1 1/2 0.90x38 mm needle	8680075449571	Rusting Steel	Yellow	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
449830	Green 21Gx1 1/2 0.80x38 mm needle	8680075449830	Rusting Steel	Green	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
447119	Green 21Gx1 1/2 0.80x16 mm needle	8680075447119	Rusting Steel	Green	59230	205*85*86	100/501	425*460*461	10000/12001	5 years
449847	Black 22Gx1 1/4 0.70x32 mm needle	8680075449847	Rusting Steel	Black	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
448277	Blue 23G 11/4 0.60x32mm needle	8680075448277	Rusting Steel	Blue	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
448260	Blue 23G 1 0.60x25 mm needle	8680075448260	Rusting Steel	Blue	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
448253	Orange 25G 1 0.50x25mm needle	8680075448253	Rusting Steel	Orange	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
448345	Brown 26G 1/2 0.45x13mm needle	8680075448345	Rusting Steel	Brown	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
448338	Grey 27G1/2 0.40x40mm needle	8680075448338	Rusting Steel	Grey	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
448321	Grey 27G 2 0.40x50mm needle	8680075448321	Rusting Steel	Grey	59230	205*85*85	100/500	425*460*460	10000/12000	5 years
449496	1 ml 3P 26Gx 1/2 mm needle Injector	8680075449496	PP_gasket	Brown	47017	148*158*180	100	615*380*485	4000	5 years
447317	1 ml 3P 30Gx 1/2 mm needle Injector (0,30 x 8 mm)	8680075447317	PP_gasket	light yellow	47017	148*158*180	100	615*380*485	4000	5 years
448659	1 ml 3P 30Gx 1/2 mm needle Injector (0,30 x 13 mm)	8680075448659	PP_gasket	light yellow	47017	148*158*180	100	615*380*485	4000	5 years
449540	Injector 2ml needle-free	8680075449540	PP_gasket	-	47017	148*226*185	350	615*380*486	3500	5 years
447324	Injector 2 ml Pink (1,20 x 16 mm)	8680075447324	PP_gasket	pink	47017	148*158*180	350	615*380*485	3500	5 years
449809	Injector 2ml Pink (1,20 x 38 mm)	8680075449809	PP_gasket	pink	47017	148*158*180	350	615*380*485	3500	5 years
449816	Injector 2ml Yellow (0,90 x 38 mm)	8680075449816	PP_gasket	Yellow	47017	148*158*180	350	615*380*485	3500	5 years
449632	Injector 2ml Green (0,80 x 16 mm)	8680075449632	PP_gasket	Green	47017	148*158*180	350	615*380*485	3500	5 years
449908	Injector 2ml Green (0,80 x 38 mm)	8680075449908	PP_gasket	Green	47017	148*158*180	350	615*380*485	3500	5 years
449861	Injector 2ml Black (0,70 x 32 mm)	8680075449861	PP_gasket	Black	47017	148*158*180	350	615*380*485	3500	5 years
449793	Injector 2ml Blue (0,60 x 25 mm)	8680075449793	PP_gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
449779	Injector 2ml Blue (0,60 x 32 mm)	8680075449779	PP_gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
448352	Injector 2ml Orange (0,50 x 25 mm)	8680075448352	PP_gasket	Orange	47017	148*158*180	350	615*380*485	3500	5 years
448376	Injector 2ml Brown (0,45 x 13 mm)	8680075448376	PP_gasket	Brown	47017	148*158*180	350	615*380*485	3500	5 years
448147	Injector 2ml Grey (0,40 x 40 mm)	8680075448147	PP_gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
449687	Injector 2ml Grey (0,40 x 50 mm)	8680075449687	PP_gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
449649	Injector 2ml Luer Lock needle-free	8680075449649	PP_gasket	-	47017	148*158*180	350	615*380*485	3500	5 years
449618	Injector 2ml Luer Lock Pink (1,20 x 38 mm)	8680075449618	PP_gasket	pink	47017	148*158*180	350	615*380*485	3500	5 years
449939	Injector 2ml Luer Lock Yellow (0,90 x 38 mm)	8680075449939	PP_gasket	Yellow	47017	148*158*180	350	615*380*485	3500	5 years

Atölye Adresleri: Kocaeli Yolu No: 105
 Tel: 0262 237 79 89
 Fax: 0262 237 79 89
 E-mail: info@berikaw.com.tr
 Web: www.berikaw.com.tr



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449472	Injector 2ml Luer Lock Green (0,80 x 38 mm)	8680075449472	PP.gasket	Green	47017	148*158*180	350	615*380*485	3500	5 years
449465	Injector 2ml Luer Lock Black (0,70 x 32 mm)	8680075449465	PP.gasket	Black	47017	148*236*185	350	615*380*486	3500	5 years
448611	Injector 2ml Luer Lock Blue (0,60 x 25 mm)	8680075448611	PP.gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
448406	Injector 2ml Luer Lock Blue (0,60 x 32 mm)	8680075448406	PP.gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
449670	Injector 2ml Luer Lock Grey (0,40 x 40 mm)	8680075449670	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
448130	Injector 2ml Luer Lock Grey (0,40 x 50 mm)	8680075448130	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
183798	Blood gas injector 2 ml Black (0,70x32 mm)	8680075448086	PP.gasket,Dry Hepatin	Black	58095	148*158*180	350	615*380*485	3500	5 years
183804	Blood gas injector 2 ml Luer Lock Black (0,70x32 mm)	8680075448079	PP.gasket,Dry Hepatin	Black	58095	148*158*180	350	615*380*485	3500	5 years
447386	Injector 2,5ml Luer Lock Grey (0,40 x 40 mm)	8680075447386	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
447386	Injector 2,5ml Luer Lock Grey (0,40 x 40 mm)	8680075447386	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
447409	Injector 2,5ml Luer Lock Grey (0,40 x 50 mm)	8680075447393	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
447416	Injector 2,5ml Grey (0,40 x 40 mm)	8680075447409	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
447416	Injector 2,5ml Grey (0,40 x 50 mm)	8680075447416	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
449991	Injector 3ml needle-free	8680075449991	PP.gasket	-	47017	148*236*185	350	615*380*486	3500	5 years
449960	Injector 3ml Pink (1,20 x 38 mm)	8680075449960	PP.gasket	pink	47017	148*158*180	350	615*380*485	3500	5 years
449953	Injector 3ml Yellow (0,90 x 38 mm)	8680075449953	PP.gasket	Yellow	47017	148*158*180	350	615*380*485	3500	5 years
440984	Injector 3ml Green (0,80 x 38 mm)	8680075449984	PP.gasket	Green	47017	148*158*180	350	615*380*485	3500	5 years
449977	Injector 3ml Black (0,70 x 32 mm)	8680075449977	PP.gasket	Black	47017	148*158*180	350	615*380*485	3500	5 years
449946	Injector 3ml Blue (0,60 x 25 mm)	8680075449946	PP.gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
448307	Injector 3ml Blue (0,60 x 32 mm)	8680075448307	PP.gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
447201	Injector 3ml Luer Lock needle-free	8680075447201	PP.gasket	-	47017	148*158*180	350	615*380*485	3500	5 years
447126	Injector 3ml Luer Lock Pink (1,20 x 38 mm)	8680075447126	PP.gasket	pink	47017	148*158*180	350	615*380*485	3500	5 years
447133	Injector 3ml Luer Lock Yellow (0,90 x 38 mm)	8680075447133	PP.gasket	Yellow	47017	148*158*180	350	615*380*485	3500	5 years
447140	Injector 3ml Luer Lock Green (0,80 x 38 mm)	8680075447140	PP.gasket	Green	47017	148*158*180	350	615*380*485	3500	5 years
447157	Injector 3ml Luer Lock Blue (0,70 x 32 mm)	8680075447157	PP.gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
447164	Injector 3ml Luer Lock Blue (0,60 x 25 mm)	8680075447164	PP.gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
447171	Injector 3ml Luer Lock Blue (0,60 x 32 mm)	8680075447171	PP.gasket	Blue	47017	148*158*180	350	615*380*485	3500	5 years
447188	Injector 3ml Luer Lock Grey (0,40 x 40 mm)	8680075447188	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
447195	Injector 3ml Luer Lock Grey (0,40 x 50 mm)	8680075447195	PP.gasket	Grey	47017	148*158*180	350	615*380*485	3500	5 years
449333	Injector 5ml needle-free	8680075449333	PP.gasket	-	47017	148*236*185	250	615*380*486	2500	5 years
447331	Injector 5 ml Pink (1,20 x 16 mm)	8680075447331	PP.gasket	pink	47017	148*158*180	250	615*380*485	2500	5 years
448215	Injector 5ml Pink (1,20 x 22 mm)	8680075447353	PP.gasket	pink	47017	148*158*180	250	615*380*485	2500	5 years
448215	Injector 5ml Pink (1,20 x 38 mm)	8680075448215	PP.gasket	pink	47017	148*158*180	250	615*380*485	2500	5 years



PRODUCT LIST

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449489	Injector 5ml Yellow (0,90 x 38 mm)	8680075449489	PP.gasket	Yellow	47017	148*158*180	250	615*380*485	2500	5 years
448161	Injector 5ml Green (0,80 x 16 mm)	8680075448161	PP.gasket	Green	47017	148*158*180	250	615*380*485	2500	5 years
449922	Injector 5ml Green (0,80 x 38 mm)	8680075449922	PP.gasket	Green	47017	148*158*180	250	615*380*485	2500	5 years
449885	Injector 5ml Black (0,70 x 32 mm)	8680075449885	PP.gasket	Black	47017	148*158*180	250	615*380*485	2500	5 years
448383	Injector 5ml Blue (0,60 x 25 mm)	8680075448383	PP.gasket	Blue	47017	148*158*180	250	615*380*485	2500	5 years
448890	Injector 5ml Blue (0,60 x 32 mm)	8680075448890	PP.gasket	Blue	47017	148*158*180	250	615*380*485	2500	5 years
448192	Injector 5ml Luer Lock needle-free	8680075448192	PP.gasket	-	47017	148*158*180	250	615*380*485	2500	5 years
448185	Injector 5ml Luer Lock Pink (1,20 x 38 mm)	8680075448185	PP.gasket	pink	47017	148*158*180	250	615*380*485	2500	5 years
448178	Injector 5ml Luer Lock Yellow (0,90 x 38 mm)	8680075448178	PP.gasket	Yellow	47017	148*158*180	250	615*380*485	2500	5 years
448154	Injector 5ml Luer Lock Green (0,80 x 38 mm)	8680075448154	PP.gasket	Green	47017	148*158*180	250	615*380*485	2500	5 years
448123	Injector 5ml Luer Lock Black (0,70 x 32 mm)	8680075448123	PP.gasket	Black	47017	148*158*180	250	615*380*485	2500	5 years
44816	Injector 5ml Luer Lock Blue (0,60 x 25 mm)	8680075448116	PP.gasket	Blue	47017	148*158*180	250	615*380*485	2500	5 years
448369	Injector 5ml Luer Lock Blue (0,60 x 32 mm)	8680075448369	PP.gasket	Blue	47017	148*158*180	250	615*380*485	2500	5 years
449519	Injector 10ml needle-free	8680075449519	PP.gasket	-	47017	148*236*184	200	615*380*485	1600	5 years
447423	Injector 10ml Pink (1,20 x 16 mm)	8680075447423	PP.gasket	pink	47017	148*236*184	200	615*380*485	1600	5 years
448208	Injector 10ml Pink (1,20 x 25 mm)	8680075447560	PP.gasket	pink	47017	148*236*184	200	615*380*485	1600	5 years
448208	Injector 10ml Pink (1,20 x 38 mm)	8680075448208	PP.gasket	pink	47017	148*236*184	200	615*380*485	1600	5 years
449564	Injector 10ml Yellow (0,90 x 38 mm)	8680075449564	PP.gasket	Yellow	47017	148*236*184	200	615*380*485	1600	5 years
449915	Injector 10ml Green (0,80 x 38 mm)	8680075449915	PP.gasket	Green	47017	148*236*184	200	615*380*485	1600	5 years
449878	Injector 10ml Black (0,70 x 32 mm)	8680075449878	PP.gasket	Black	47017	148*236*184	200	615*380*485	1600	5 years
448222	Injector 10ml Blue (0,60 x 25 mm)	8680075448222	PP.gasket	Blue	47017	148*236*184	200	615*380*485	1600	5 years
448239	Injector 10ml Blue (0,60 x 32 mm)	8680075448239	PP.gasket	Blue	47017	148*236*184	200	615*380*485	1600	5 years
448314	Injector 10ml Luer Lock needle-free	8680075448314	PP.gasket	-	47017	148*236*184	200	615*380*485	1600	5 years
448291	Injector 10ml Luer Lock Pink (1,20 x 38 mm)	8680075448291	PP.gasket	pink	47017	148*236*184	200	615*380*485	1600	5 years
448284	Injector 10ml Luer Lock Yellow (0,90 x 38 mm)	8680075448284	PP.gasket	Yellow	47017	148*236*184	200	615*380*485	1600	5 years
448246	Injector 10ml Luer Lock Green (0,80 x 38 mm)	8680075448246	PP.gasket	Green	47017	148*236*184	200	615*380*485	1600	5 years
448109	Injector 10ml Luer Lock Black (0,70 x 32 mm)	8680075448109	PP.gasket	Black	47017	148*236*184	200	615*380*485	1600	5 years
448093	Injector 10ml Luer Lock Blue (0,60 x 25 mm)	8680075448093	PP.gasket	Blue	47017	148*236*184	200	615*380*485	1600	5 years
448628	Injector 10ml Luer Lock Blue (0,60 x 32 mm)	8680075448628	PP.gasket	Blue	47017	148*236*184	200	615*380*485	1600	5 years
449526	Injector 20ml needle-free	8680075449526	PP.gasket	-	47017	148*236*185	125	615*380*485	1000	5 years
449762	Injector 20ml Pink (1,20 x 38 mm)	8680075449762	PP.gasket	pink	47017	148*158*180	125	615*380*485	1000	5 years
449755	Injector 20ml Yellow (0,90 x 38 mm)	8680075449755	PP.gasket	Yellow	47017	148*158*180	125	615*380*485	1000	5 years

