

Genject®



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Genject®

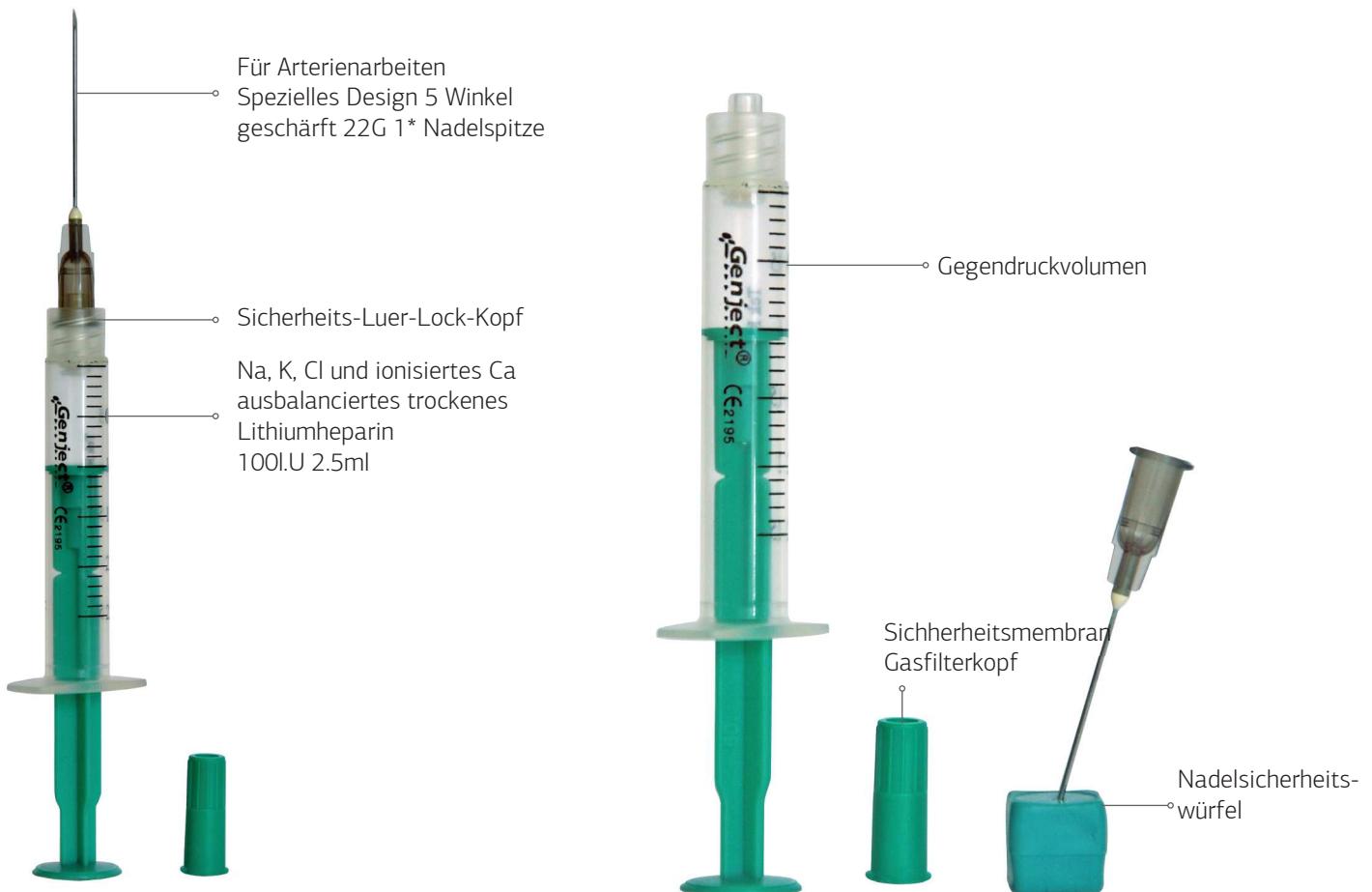


Blutgasspritzen • FULL

Blood Gas Syringes • FULL

Jede der Blutgasspritzen der Marke Genject wurde so entwickelt, dass die Analysesicherheit auf einem Referenzprodukt niveau gewährleistet ist. Genject Blutgasspritzen enthalten Na, K, Cl und ionisiertes Ca ausgewogenes trockenes Lithiumheparin. Genject Blutgasspritzen haben umgekehrte Druckvolumen, die sich automatisch mit Arteriendruck füllen und ihren Benutzern einzigartige Einfachheit und Sicherheit mit trockenem Heparin mit sichergestelltem Elektrolytgleichgewicht bieten. Die speziell entwickelte 22G 1" Nadel, die in 5 Winkeln für Arterienarbeiten geschärft wurde, ermöglicht die Ableitung von Gas, der speziell entwickelte Membranfilter verhindert Gaslecks, sicherer Luer-Lock-Verschlusskopf und Nadelsicherheitswürfel.

Seri No	ml	G	mm
8699931759600	2.5	22 ♦	25



Blutgasspritzen • SIMPLE

Blood Gas Syringes • SIMPLE

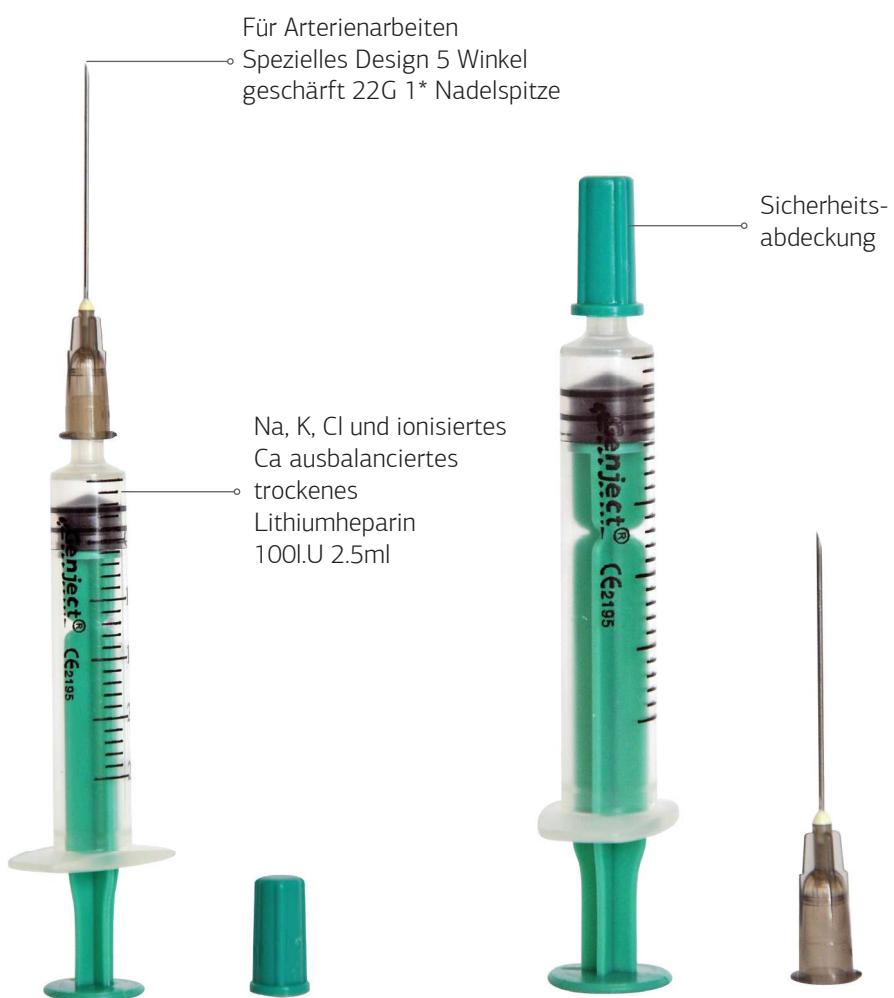


Jede der Blutgasspritzen der Marke Genject wurde so entwickelt, dass die Analysesicherheit auf einem Referenzproduktneiveau gewährleistet ist. Genject Blutgasspritzen enthalten Na, K, Cl und ionisiertes Ca ausgewogenes trockenes Lithiumheparin. Es bietet einzigartige Leichtigkeit und Sicherheit für

seine Benutzer mit trockenem Heparin mit sichergestelltem Elektrolytgleichgewicht. Speziell entwickelte 22G 1" Nadel, in 5 Winkeln geschärft für Arterienarbeiten und Farbdesign passend zum Konzept.

Die Genject-Trockenheparin-Blutgasspritze der neuen Generation bietet ihren Benutzern einen funktionalen Unterschied in Bezug auf die Sicherheit während und nach der Anwendung und bietet auch den sichersten Komfort für die Umwelt und die menschliche Gesundheit. Alle Blutgasspritzen der Marke Genject sind mit der neuesten Technologie ausgestattet und werden in den Genject-Werken nach GMP-Standards hergestellt.

Seri No	ml	G	mm
8699931759617	2.5	22 ♦	25



Each of the Blood Gas Syringes bearing the Genject brand has been designed in a manner ensuring analysis safety at a reference product level. Genject Blood Gas Syringes contain Na, K, Cl and Ionized Ca balanced dry lithium heparin. It provides unique ease and safety for its user with dry heparin with ensured electrolyte balance, specially designed 22G 1" needle sharpened at 5 angles for artery works and color design suitable for its concept.

The new generation Genject dry heparin blood gas syringe provides its users functional difference in terms of safety during and after application and it also provides the comfort that is the most safest for the environment and human health. All blood gas syringes bearing the Genject brand are equipped with the latest technology and are manufactured at the Genject plants with GMP standards.

2-teilige Spritzen

2 Part Syringes



Einwegspritzen der Marke Genject ohne Gummi, werden berührungslos nach CE-Standards in Genject-Produktionsstätten die mit neuester Technologie ausgestattet sind, nach GMP-Standards, hergestellt. Spritzen der Marke Genject ohne Gummi sind mit Ethylenoxid-Gassterilisation 5 Jahre haltbar. Luer-Adapter mit einer Neigung von 6% und den Optionen mit zentrischem oder exzentrischem Lauf, es ist ungiftig und pyrogenfrei. Die Spritzen der Marke Genject ohne Gummi erleichtern die Bewegung des Kolbens mit dem speziell entwickelten medizinischen Silikon und priorisieren immer Qualität und Benutzerfreundlichkeit.

Genject brand disposable syringes without rubber are manufactured without being touched in accordance with CE standards at Genject production facilities with GMP standards equipped with the latest technology. Genject brand syringes without rubber have 5 year shelf lives with ethylene oxide gas sterilization. With the Luer adaptor that has a slope of 6% and centric or eccentric barrel options, it is non toxic and pyrogen free. The Genject brand syringes without rubber facilitate the motion of the piston with the specially designed medical grade silicon, and always prioritizes quality and ease of use.

Körper: → Polypropylen (medizinische Qualität)

Kolben: → Polyethylen (medizinische Qualität)

Blisterfolie: → Medizinische Qualität (transparente Folie)

Blisterpapier: → Speziell für die Ethylenoxid-Gassterilisation medizinisches Papier

Nadelspitze: → Nahtloser Edelstahl AISI 316

Barkod	ml	G	mm
8699931751604	2	21 ◆	38
8699931751611	2	22 ♦	38
8699931751628	2	23 ▲	32
8699931751635	5	18 ♡	38
8699931751642	5	20 ▲	38
8699931751659	5	21 ◆	38
8699931751666	5	22 ♦	38
8699931751673	5	23 ▲	32
8699931751697	10	18 ♡	38
8699931751703	10	21 ◆	38
8699931751710	10	22 ♦	38
8699931751727	10	23 ▲	32



3-teilige Spritzen

3 Part Syringes



Barkod	ml	G	mm
8699931753004	2	20 ◆	38
8699931753011	2	21 ◆	38
8699931753028	2	22 ◆	38
8699931753035	2	23 ◆	32
8699931753042	5	20 ◆	38
8699931753059	5	21 ◆	38
8699931753066	5	22 ◆	38
8699931753073	10	23 ◆	32
8699931753097	10	18 ◆	38
8699931753103	10	20 ◆	38
8699931753110	10	21 ◆	38
8699931753127	10	22 ◆	38
8699931753134	20	23 ◆	32
8699317531158	20	18 ◆	38
8699931753165	20	20 ◆	38
8699931753172	20	21 ◆	38
8699931753189	20	22 ◆	38

Einwegspritzen Gummi der Marke Genject werden berührungslos nach CE-Standards in Genject-Produktionsstätten die mit neuester Technologie ausgestattet sind, nach GMP-Standards, hergestellt. Spritzen der Marke Genject sind mit Ethylenoxid-Gassterilisation 5 Jahre haltbar. Luer-Adapter mit einer Neigung von 6% und den Optionen mit zentrischem oder exzentrischem Lauf, es ist ungiftig und pyrogenfrei. Die Spritzen der Marke Genject ohne Gummi erleichtern die Bewegung des Kolbens mit dem speziell entwickelten medizinischen Silikon und priorisieren immer Qualität und Benutzerfreundlichkeit.

Körper: → Polypropylen (medizinische Qualität)

Kolben: → Polyethylen (medizinische Qualität)

Dichtung: → Latex frei

Blisterfolie: → Medizinische Qualität (transparente Folie)

Blisterpapier: → Speziell für die Ethylenoxid-Gassterilisation medizinisches Papier

Nadelspitze: → Nahtloser Edelstahl AISI 316

Genject brand disposable syringes rubber are manufactured without being touched in accordance with CE standards at Genject production facilities with GMP standards equipped with the latest technology. Genject brand syringes rubber have 5 year shelf lives with ethylene oxide gas sterilization. With the Luer adaptor that has a slope of 6% and centric or eccentric barrel options, it is non toxic and pyrogen free. The Genject brand syringes without rubber facilitate the motion of the piston with the specially designed medical grade silicon, and always prioritizes quality and ease of use.



Impfspritzen

Vaccination Syringes



Barcode	ml	G	mm
8699931757019	2	25 ◆	25
8699931757026	2	25 ◆	16



Veterinärspritzen

Veterinary Syringes



Barcode	ml	G	mm
8699931756005	2	21 ◆	16
8699931756012	5	21 ◆	16
8699931756029	10	18 ♦	38
8699931756036	20	18 ♦	38
8699931756043	50	18 ♦	38



Dentalspritzen

Dental Syringes



Die Dentalspritzen der Marke Genject wurden für eine komfortable und sichere Anwendung durch angesehene Zahnärzte hergestellt. In der Produktion wird es mit drei speziell entwickelten 40 mm und 27 g 50 mm Nadeloptionen präsentiert, die für den zahnärztlichen Gebrauch geeignet sind.

Die beiden Laufvarianten Luer und Luer Lock wurden erneut vorgestellt, um vorzubeugen, dass Ärzte Schwierigkeiten haben. Beim abschließbaren Luer-Lock-Modell wird eine einfache Handhabung gewährleistet, indem verhindert wird, dass sich die Nadel vom Zylinder löst.

Der Hauptgrund dafür, dass Dentalspritzen der Marke Genject bevorzugt werden, ist zweifellos das spezielle Design der Nadel.

Barcode	ml	G	mm
8699931754308	2	27 ♦	40
8699931754315	2	27 ♦	50

The Genject brand dental syringes have been produced for comfortable and safe use by esteemed dentists. In production, it is presented with the specially designed 40mm and 27g 50mm needle options suitable for dental use.

The two barrel options of luer barrel and luer lock barrel have been presented again for the purpose of preventing doctors from experiencing difficulties. With the lockable luer-lock model ease of use is ensured by preventing the needle separating from the barrel.

The greatest reason for Genject brand dental syringes being preferred is undoubtedly the special design of its needle.



50 ml Spritzen

50 ml Syringes



50 ml Einwegspritzen Gummi der Marke Genject® werden berührungslos nach CE-Standards in Genject-Produktionsstätten die mit neuester Technologie ausgestattet sind, nach GMP-Standards, hergestellt. 50 ml Spritzen der Marke Genject® sind mit Ethylenoxid-Gassterilisation 5 Jahre haltbar. Mit dem Luer-Adapter mit einer Neigung von 6% und wahlweise mit zentrischem oder exzentrischem Lauf ist er ungiftig und pyrogenfrei. Die Spritzen der Marke Genject® ohne Gummi erleichtern die Bewegung des Kolbens mit dem speziell entwickelten medizinischen Silikon und legen immer Wert auf Qualität und Benutzerfreundlichkeit.

Genject® brand 50ml disposable syringes rubber are manufactured without being touched in accordance with CE standards at Genject® production facilities with GMP standards equipped with the latest technology. Genject® brand 50ml syringes rubber have 5 year shelf lives with ethylene oxide gas sterilization. With the Luer adaptor that has a slope of 6% and centric or eccentric barrel options, it is non toxic and pyrogen free. The Genject® brand syringes without rubber facilitate the motion of the piston with the specially designed medical grade silicon, and always prioritizes quality and ease of use.

Barcode	ml	G	mm
8699931754018	50	18 ♦	38
8699931754025	50	20 ♦	38
8699931754032	50	21 ♦	38
8699931758009	50		KATHETERSPRITZE



Zertifikate

Certificates



QUALITÄTSRICHTLINIE

Unser Unternehmen hat sich die Kontinuität des Vertrauens, das es aufgebaut hat, und die Qualität, die zum Symbol dieses Vertrauens geworden ist, zum Prinzip gemacht.

Mit dem Qualitätsmanagementsystem zielt es darauf ab, im nationalen und internationalen Bereich stetig zu wachsen und sich weiterzuentwickeln.

Unser Unternehmen steht für

- ⌚ Einhaltung aller gesetzlichen Auflagen,
- ⌚ Kundenzufriedenheit,
- ⌚ Konstante Entwicklung,
- ⌚ Effizienzsteigerung,
- ⌚ Ständige Weiterbildung,
- ⌚ Qualitätsprodukte,
- ⌚ Aufrechterhaltung der Effizienz durch die ständige Überprüfung des Qualitätsmanagementsystems als Richtlinie

QUALITY POLICY

Our company has adopted as a principle the continuity of the confidence it has built and quality, which has become the icon of this confidence.

With the quality management system, it aims to constantly grow and develop in the national and international arena

Our company has designated

- ⌚ Compliance with all Legal Conditions,
- ⌚ Customer Satisfaction,
- ⌚ Constant Development,
- ⌚ Efficiency Increasing,
- ⌚ Constant Training,
- ⌚ Pout Quality,
- ⌚ Maintaining Efficiency through the Constant Review of the Quality Management System as policy.

Genject®

Wir Respektieren Ihr Vertrauen
We Respect Your Trust





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GNJT-03-TDS TECHNICAL DATA SHEET

STERILE WITH / WITHOUT NEEDLE – WITH / WITHOUT GASKET HYPODERMIC
DISPOSABLE SYRINGE

STERILE CATHETER SYRINGE WITHOUT NEEDLE
STERILE NEEDLE TIP

1. PRODUCT DESCRIPTION

GENJECT syringe products;

- Piston part is made of high density polyethylene,
- Body part is made of high density polypropylene.
- Gasket isoprene rubber (optional),
- Needle (optional) is supplied in stainless steel conforming to the ISO 7864 standard.
- Blister paper as packaging material,
- Silicon oil (Polysiloxane and Hydracarbon) is used as lubricant.
- Silk PET with silk-screen prints supplied by the supplier, and
- It is made using black PP serigraphy ink.

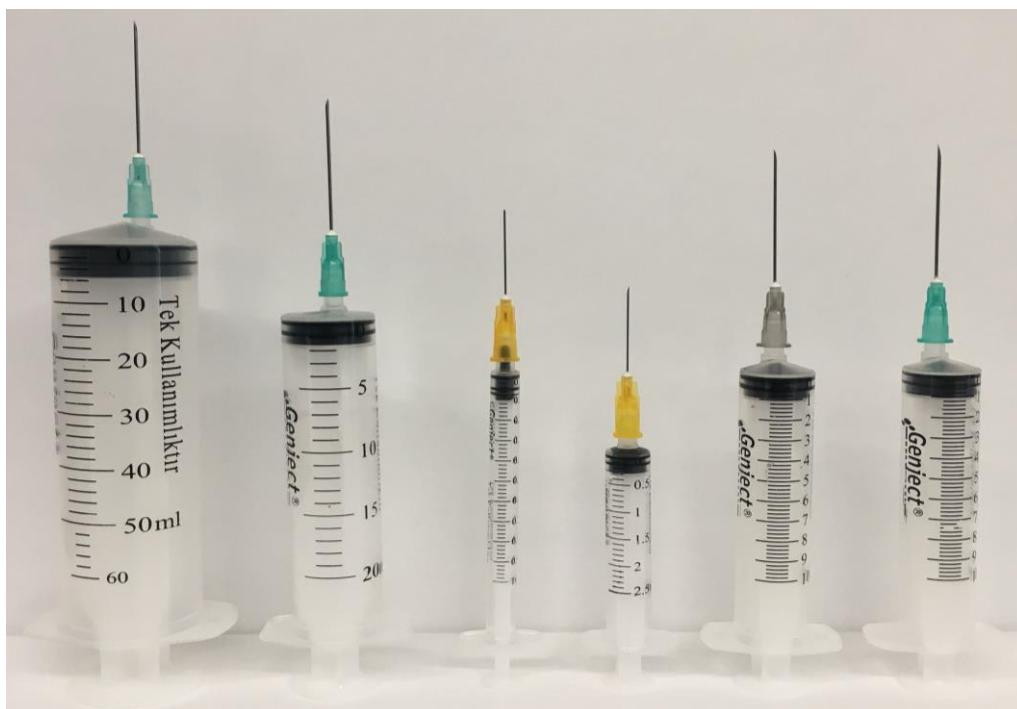


Figure 1. Example of Disposable Hypodermic Syringe

Disposable hypodermic needles products, with color connector in accordance with ISO 6009, 6% inclined needle tip, made of stainless steel in accordance with ISO 9626 and ISO 7864 standards, high density polypropylene luer connector and also high density includes transparent polypropylene needle protective cover.

The final Syringe product in accordance with the ISO 7886 standard, which is assembled, is obtained. For a disposable hypodermic syringe, the luer tip can be centric or eccentric. In Nutrition Syringe products, the luer tip is centric and there is no needle.

The label information, symbols and markings of the syringe packaging are printed on the back of the blister film-coated packaging paper in accordance with the TS EN ISO 15223-1 standard.

1.1. GMDN CODE

The GMDN Code of Needle / Without Needle – With Gasket / Without Gasket Hypodermic Disposable Syringes is 35904.

Explanation

35904- Syringe, hypodermic, metered delivery DESCRIPTION: It is an instrument consisting of a graduated cylinder and piston designed to deliver a precisely metered dose (infusion) during an injection administration. CATEGORIES: 10-Disposable devices.

The GMDN Code of the hypodermic needle is 59230.

Explanation

59230-Injection needle, disposable, sterile DESCRIPTION: With syringes, secondary drug delivery sets or intravenous blood collection device (e.g. blood collection adapters or holders) to draw fluid from a patient or to deliver or prepare fluid / drug therapy / medication to a patient) is a sterile, sharply bevelled, hollow tubular metal device intended for use together. It is a single use device. CATEGORIES: 10-Disposable devices

1.2. CLASSIFICATION

Since our products are Class IIa medical devices, 93/42 / EEC Medical Device Directive Annex V Full Quality Assurance Module has been chosen as the conformity assessment route.

1.3. CERTIFICATION

Genject Manufacturer	ISO Certification	CE Marking	Genject Manufacturing Site
Genject Sağlık Ürünleri ve Kimya Sanayi ve	PCA-Body No:MSCB-103 Certificate No: TC-	UDEM-Body No:2292 Certificate No:	Alçı OSB Mah. 2013 Cad. No:24/1

Handelsgesellschaft	75380- ISO 13485:2016	N.2021.106.14344-93/42/EEC Annex V	
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1.4. PRODUCT LIST

TWO PARTS SYRINGE (WITHOUT GASKET)							
S/N	PRODUCT CODE	BRAND	MODEL	REFERENCE NO	PRODUCT TYPE	BOX (units)	CASE (units)
1	152MML128	GENJECT	2 ML 18 G / 38 mm 2P Syringe	218382P	WITHOUT GASKET, WITH NEEDLE	250	1000
2	152MML129	GENJECT	2 ML 21 G / 16 mm 2P Syringe	221162P	WITHOUT GASKET, WITH NEEDLE	250	1000
3	152MML002	GENJECT	2 ML 21 G / 38 mm 2P Syringe	221382P	WITHOUT GASKET, WITH NEEDLE	250	1000
4	152MML130	GENJECT	2 ML 22 G / 38 mm 2P Syringe	222382P	WITHOUT GASKET, WITH NEEDLE	250	1000
5	152MML063	GENJECT	2 ML 23 G / 32 mm 2P Syringe	223322P	WITHOUT GASKET, WITH NEEDLE	250	1000
6	152MML064	GENJECT	2,5 ML 18 G / 38 mm 2P Syringe	20518382P	WITHOUT GASKET, WITH NEEDLE	250	1000
7	152MML065	GENJECT	2,5 ML 21 G / 16 mm 2P Syringe	20521162P	WITHOUT GASKET, WITH NEEDLE	250	1000
8	152MML066	GENJECT	2,5 ML 21 G / 38 mm 2P Syringe	20521382P	WITHOUT GASKET, WITH NEEDLE	250	1000
9	152MML067	GENJECT	2,5 ML 22 G / 38 mm 2P Syringe	20522382P	WITHOUT GASKET, WITH NEEDLE	250	1000
10	152MML068	GENJECT	2,5 ML 23 G / 32 mm 2P Syringe	20523322P	WITHOUT GASKET, WITH NEEDLE	250	1000
11	152MML069	GENJECT	5 ML 18 G / 38 mm 2P Syringe	518382P	WITHOUT GASKET, WITH NEEDLE	250	1000
12	152MML070	GENJECT	5 ML 20 G / 38 mm 2P Syringe	520382P	WITHOUT GASKET, WITH NEEDLE	250	1000
13	152MML071	GENJECT	5 ML 21 G / 16 mm 2P Syringe	521162P	WITHOUT GASKET, WITH NEEDLE	250	1000
14	152MML014	GENJECT	5 ML 21 G / 38 mm 2P Syringe	521382P	WITHOUT GASKET, WITH NEEDLE	250	1000
15	152MML015	GENJECT	5 ML 22 G / 38 mm 2P Syringe	522382P	WITHOUT GASKET, WITH NEEDLE	250	1000
16	152MML072	GENJECT	5 ML 23 G / 32 mm 2P Syringe	523322P	WITHOUT GASKET, WITH NEEDLE	250	1000
17	152MML073	GENJECT	10 ML 18 G / 38 mm 2P Syringe	1018382P	WITHOUT GASKET, WITH NEEDLE	250	1000
18	152MML026	GENJECT	10 ML 21 G / 38 mm 2P Syringe	1021382P	WITHOUT GASKET, WITH NEEDLE	250	1000
19	152MML027	GENJECT	10 ML 22 G / 38	1022382P	WITHOUT GASKET,	250	1000

			mm 2P Syringe		WITH NEEDLE		
20	152MML074	GENJECT	10 ML 23 G / 32 mm 2P Syringe	1023322P	WITHOUT GASKET, WITH NEEDLE	250	1000
21	152MML037	GENJECT	20 ML 21G / 38mm 2P Syringe	2021382P	WITHOUT GASKET, WITH NEEDLE	100	800
22	152MML075	GENJECT	25 ML 18 G / 38 mm 2P Syringe	2518382P	WITHOUT GASKET, WITH NEEDLE	100	800

THREE PARTS SYRINGE (WITH GASKET)

S/N	PRODUCT CODE	BRAND	MODEL	REFERANCE NO	PRODUCT TYPE	BOX (units)	CASE (units)
1	152MML076	GENJECT	1 ML 26 G / 13 mm 3P Syringe	126133P	WITH GASKET WITH NEEDLE	500	2000
2	152MML077	GENJECT	1 ML 29 G / 13 mm 3P Syringe	129133P	WITH GASKET WITH NEEDLE	500	2000
3	152MML078	GENJECT	1 ML 30 G / 8 mm 3P Syringe	13083P	WITH GASKET WITH NEEDLE	500	2000
4	152MML131	GENJECT	1 ML 23 G / 25mm Syringe	123253P	WITH GASKET WITH NEEDLE	500	2000
5	152MML132	GENJECT	1 ML 23 G / 32mm Syringe	123323P	WITH GASKET WITH NEEDLE	500	2000
6	152MML133	GENJECT	1 ML 25 G / 25mm Syringe	125253P	WITH GASKET WITH NEEDLE	500	2000
7	152MML134	GENJECT	1 ML 25 G / 16 mm Syringe	125163P	WITH GASKET WITH NEEDLE	500	2000
8	152MML079	GENJECT	2 ML 3P Syringe	23P	WITH GASKET WITHOUT NEEDLE	250	1000
9	152MML080	GENJECT	2 ML 18 G / 38 mm 3P Syringe	218383P	WITH GASKET WITH NEEDLE	250	1000
10	152MML081	GENJECT	2 ML 20 G / 38 mm 3P Syringe	220383P	WITH GASKET WITH NEEDLE	250	1000
11	152MML086	GENJECT	2 ML 21 G / 38 mm 3P Syringe	221383P	WITH GASKET WITH NEEDLE	250	1000
12	152MML004	GENJECT	2 ML 21 G / 16 mm 3P Syringe	221163P	WITH GASKET WITH NEEDLE	250	1000
13	152MML082	GENJECT	2 ML 22 G / 32 mm 3P Syringe	222323P	WITH GASKET WITH NEEDLE	250	1000
14	152MML089	GENJECT	2 ML 22 G / 38 mm 3P Syringe	222383P	WITH GASKET WITH NEEDLE	250	1000
15	152MML090	GENJECT	2 ML 23 G / 25 mm 3P Syringe	223253P	WITH GASKET WITH NEEDLE	250	1000
16	152MML091	GENJECT	2 ML 23 G / 32 mm 3P Syringe	223323P	WITH GASKET WITH NEEDLE	250	1000
17	152MML092	GENJECT	2 ML 25 G / 16 mm 3P Syringe	225163P	WITH GASKET WITH NEEDLE	250	1000

18	152MML093	GENJECT	2 ML 25 G / 25 mm 3P Syringe	225253P	WITH GASKET WITH NEEDLE	250	1000
19	152MML094	GENJECT	2 ML 27 G / 40 mm 3P Syringe	227403P	WITH GASKET WITH NEEDLE	250	1000
20	152MML095	GENJECT	2 ML 27 G / 50 mm 3P Syringe	227503P	WITH GASKET WITH NEEDLE	250	1000
21	152MML083	GENJECT	2,5 ML 3P Syringe	2053P	WITH GASKET WITHOUT NEEDLE	250	1000
22	152MML084	GENJECT	2,5 ML 18 G / 38 mm 3P Syringe	20518383P	WITH GASKET WITH NEEDLE	250	1000
23	152MML085	GENJECT	2,5 ML 20 G / 38 mm 3P Syringe	20520383P	WITH GASKET WITH NEEDLE	250	1000
24	152MML006	GENJECT	2,5 ML 21 G / 38 mm 3P Syringe	20521383P	WITH GASKET WITH NEEDLE	250	1000
25	152MML087	GENJECT	2,5 ML 21 G / 16 mm 3P Syringe	20521163P	WITH GASKET WITH NEEDLE	250	1000
26	152MML088	GENJECT	2,5 ML 22 G / 32 mm 3P Syringe	20522323P	WITH GASKET WITH NEEDLE	250	1000
27	152MML008	GENJECT	2,5 ML 22 G / 38 mm 3P Syringe	20522383P	WITH GASKET WITH NEEDLE	250	1000
28	152MML009	GENJECT	2,5 ML 23 G / 25 mm 3P Syringe	20523253P	WITH GASKET WITH NEEDLE	250	1000
29	152MML010	GENJECT	2,5 ML 23 G / 32 mm 3P Syringe	20523323P	WITH GASKET WITH NEEDLE	250	1000
30	152MML011	GENJECT	2,5 ML 25 G / 16 mm 3P Syringe	20525163P	WITH GASKET WITH NEEDLE	250	1000
31	152MML012	GENJECT	2,5 ML 25 G / 25 mm 3P Syringe	20525253P	WITH GASKET WITH NEEDLE	250	1000
32	152MML052	GENJECT	2,5 ML 27 G / 40 mm 3P Syringe	20527403P	WITH GASKET WITH NEEDLE	250	1000
33	152MML056	GENJECT	2,5 ML 27 G / 50 mm 3P Syringe	20527503P	WITH GASKET WITH NEEDLE	250	1000
34	152MML123	GENJECT	2,5 ML 27 G / 40 mm LUER-LOCK 3P Syringe	20527403PL	WITH GASKET WITH NEEDLE LUER-LOCK	250	1000
35	152MML124	GENJECT	2,5 ML 27 G / 50 mm LUER-LOCK 3P Syringe	20527503PL	WITH GASKET WITH NEEDLE LUER-LOCK	250	1000
36	152MML096	GENJECT	5 ML 3P Syringe	53P	WITH GASKET WITHOUT NEEDLE	250	1000
37	152MML097	GENJECT	5 ML 18 G / 38 mm 3P Syringe	518383P	WITH GASKET WITH NEEDLE	250	1000
38	152MML016	GENJECT	5 ML 20 G / 38 mm 3P Syringe	520383P	WITH GASKET WITH NEEDLE	250	1000
39	152MML098	GENJECT	5 ML 21 G / 16 mm 3P Syringe	521163P	WITH GASKET WITH NEEDLE	250	1000
40	152MML019	GENJECT	5 ML 21 G / 38	521383P	WITH GASKET	250	1000

			mm 3P Syringe		WITH NEEDLE		
41	152MML099	GENJECT	5 ML 22 G / 32 mm 3P Syringe	522323P	WITH GASKET WITH NEEDLE	250	1000
42	152MML021	GENJECT	5 ML 22 G / 38 mm 3P Syringe	522383P	WITH GASKET WITH NEEDLE	250	1000
43	152MML100	GENJECT	5 ML 23 G / 25 mm 3P Syringe	523253P	WITH GASKET WITH NEEDLE	250	1000
44	152MML022	GENJECT	5 ML 23 G / 32 mm 3P Syringe	523323P	WITH GASKET WITH NEEDLE	250	1000
45	152MML101	GENJECT	10 ML 3P Syringe	103P	WITH GASKET WITHOUT NEEDLE	250	1000
46	152MML029	GENJECT	10 ML 18 G / 38 mm 3P Syringe	1018383P	WITH GASKET WITH NEEDLE	250	1000
47	152MML030	GENJECT	10 ML 20 G / 38 mm 3P Syringe	1020383P	WITH GASKET WITH NEEDLE	250	1000
48	152MML032	GENJECT	10 ML 21 G / 38 mm 3P Syringe	1021383P	WITH GASKET WITH NEEDLE	250	1000
49	152MML102	GENJECT	10 ML 22 G / 32 mm 3P Syringe	1022323P	WITH GASKET WITH NEEDLE	250	1000
50	152MML034	GENJECT	10 ML 22 G / 38 mm 3P Syringe	1022383P	WITH GASKET WITH NEEDLE	250	1000
51	152MML103	GENJECT	10 ML 23 G / 25 mm 3P Syringe	1023253P	WITH GASKET WITH NEEDLE	250	1000
52	152MML104	GENJECT	10 ML 23 G / 32 mm 3P Syringe	1023323P	WITH GASKET WITH NEEDLE	250	1000
53	152MML105	GENJECT	20 ML 3P Syringe	203P	WITH GASKET WITHOUT NEEDLE	100	800
54	152MML106	GENJECT	20 ML 23 G / 32 mm 3P Syringe	2023323P	WITH GASKET WITH NEEDLE	100	800
55	152MML038	GENJECT	20 ML 18 G / 38 mm 3P Syringe	2018383P	WITH GASKET WITH NEEDLE	100	800
56	152MML039	GENJECT	20 ML 20 G / 38 mm 3P Syringe	2020383P	WITH GASKET WITH NEEDLE	100	800
57	152MML041	GENJECT	20 ML 21 G / 38 mm 3P Syringe	2021383P	WITH GASKET WITH NEEDLE	100	800
58	152MML048	GENJECT	20 ML 21 G / 38 mm 3P Syringe	2021383PL	WITH GASKET WITH NEEDLE LUER-LOCK	100	800
59	152MML107	GENJECT	20 ML 22 G / 38 mm 3P Syringe	2022383P	WITH GASKET WITH NEEDLE	100	800
60	152MML108	GENJECT	20 ML 23 G / 25 mm 3P Syringe	2023253P	WITH GASKET WITH NEEDLE	100	800
61	152MML109	GENJECT	50 ML 3P Syringe	503P	WITH GASKET WITHOUT NEEDLE	50	400
62	152MML043	GENJECT	50 ML 18 G / 38 mm 3P Syringe	5018383P	WITH GASKET WITH NEEDLE	50	400

63	152MML044	GENJECT	50 ML 20 G / 38 mm 3P Syringe	5020383P	WITH GASKET WITH NEEDLE	50	400
64	152MML045	GENJECT	50 ML 21 G / 38 mm 3P Syringe	5021383P	WITH GASKET WITH NEEDLE	50	400
65	152MML047	GENJECT	50 ml CATHETER	503PK	WITH GASKET WITHOUT NEEDLE	60	360
NEEDLES							
S/N	PRODUCT CODE	BRAND	MODEL	REFERANCE NO	PRODUCT TYPE	BOX (units)	CASE (units)
1	152MML110	GENJECT	18G 38mm	1838	NEEDLE	500	5000
2	152MML111	GENJECT	20G 38mm	2038	NEEDLE	500	5000
3	152MML112	GENJECT	21G 16mm	2116	NEEDLE	500	5000
4	152MML113	GENJECT	21G 38mm	2138	NEEDLE	500	5000
5	152MML114	GENJECT	22G 32mm	2232	NEEDLE	500	5000
6	152MML115	GENJECT	22G 38mm	2238	NEEDLE	500	5000
7	152MML116	GENJECT	23G 25mm	2325	NEEDLE	500	5000
8	152MML117	GENJECT	23G 32mm	2332	NEEDLE	500	5000
9	152MML118	GENJECT	25G 16mm	2516	NEEDLE	500	5000
10	152MML119	GENJECT	25G 25mm	2525	NEEDLE	500	5000
11	152MML120	GENJECT	26G 13mm	2613	NEEDLE	500	5000
12	152MML121	GENJECT	27G 40mm	2740	NEEDLE	500	5000
13	152MML122	GENJECT	27G 50mm	2750	NEEDLE	500	5000

1.5. INTENDED USE OF THE PRODUCT

Generally, the purpose of syringes used in medicine is to inject fluid into the body.

Syringes can be used with different features according to their needles. In this direction, it is used both in oral applications while being treated within the scope of oral and dental health, in the treatment of animals for veterinary purposes and, if necessary, in normal subcutaneous applications in humans for human purposes.

1.5.1. Indications

The Disposable Syringe is indicated for surgical use, vaccination, medical diagnosis and treatment, and surgical applications related to blood vessels.

Nutrition injectors are used to inject the necessary medicines or nutrients with the help of an injector by mouthing into the abdominal wall of the stomach in order to feed the patients who cannot be fed orally.

1.5.2. Name of Diseases and Conditions / Clinical Conditions Healed, Controlled or Diagnosed

It is used in the diagnosis and treatment of human diseases.

1.5.3. Patient Population and Intended Users

It can be used for patients of all age groups. It is intended for use by healthcare professionals and clinical support professionals.

1.5.4. Reusability

It has no repeated use.

1.5.5. Warnings

- Do not use torn or opened products.
- Open the package from the "Open here" section on the label.
- After removing the syringe from its packaging, check for cracks that may cause leakage.
- Take the needle out of the cover and add medicine, etc. draw the liquid into the syringe.
- Make sure that there is no air in the syringe.
- After using for injection, put the cap of the needle cover back on the needle and throw it into the safe waste box.
- Do not use again.
- Do not resterilize.
- Before using the syringe, pay attention to the warnings on the label.
- Use in accordance with the expiry date.
- Do not use the product whose shelf life has expired.
- Do not use it with other devices other than their intended use and other than their intended purpose.
- When removing the needle from its cap, make sure that the cap is not broken or cracked.
- Make sure the needle tip is not burred or blunt.

1.5.6. Disposable

It is for single use only.

1.5.7. Shelf Life

The product has a 2-year shelf life.

1.6. STERILIZATION

It is sterilized with Ethylene Oxide gas. It is not resterilized.

1.7. WORKING PRINCIPLE

When preparing the syringe for use, open the syringe package from the "open here" section indicated on the label.

To insert the needle, it is removed from its protective cover and gently pushed through the conical head of the syringe.

It is checked whether the needle is properly attached to the taper head.

The liquid to be injected is taken into the body chamber by pulling the plunger back towards the needle part.

The fluid is injected by pushing the plunger forward again with the help of the trunk ears.

1.8. BIOCOMPATABILITY

Cytotoxicity, Hemolytic Effect, Irritation, Sensitization, Acute Systemic Toxicity, Pyrogenicity, Intra-Skin Irritation Tests were performed according to ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing.

1.9. MECHANICAL STRENGTH

Mechanical strength tests were performed according to ISO 7886-1, ISO 7864, ISO 9626, ISO 6009 and ISO 80369-7 standards.

1.10. STANDARDS

S/N	STANDARDS	DESCRIPTION
1	EN ISO 13485:2016	Medical devices – Quality management Systems Requirements for Regulatory Purposes
2	EN 1041+A1:2014	Terminology, symbols and information provided with medical devices. Information supplied by the manufacturer with medical devices
3	EN ISO 10993 series	Biological evaluation of medical devices
4	EN ISO 14644-1:2016	Cleanrooms and associated controlled environments - Part 1:

		Classification of air cleanliness by particle concentration
5	EN ISO 14644-2:2016	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
6	EN ISO 14644-3:2019	Cleanrooms and associated controlled environments - Part 3: Test methods
7	EN ISO 14644-8:2013	Cleanrooms and associated controlled environments — Part 8: Classification of air cleanliness by chemical concentration (ACC)
8	EN ISO 7886-1:2018	Sterile hypodermic syringes For Single use - Part 1:Syringes for manual use
9	EN ISO 80369-7:2017	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
10	EN ISO 15223-1:2016	Sterilisation of Medical Devices – requirements for medical devices to be labelled “sterile”.
11	EN ISO 14971:2020	Medical devices - Application of risk management to medical devices
12	EN ISO 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
13	EN ISO 62366-1/AC	Medical devices - Part 1: Application of usability engineering to medical devices
14	EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
15	EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
16	EN 556-1:2009	Sterilisation of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised medical devices
17	EN ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
18	EN ISO 6009:2016	Hypodermic needles for single use — Colour coding for identification
19	EN ISO 7864:2016	Sterile hypodermic needles for single use - Requirements and test methods
20	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
21	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
22	EN 556-1/AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices
23	EN 556-1: 2009	Sterilisation of medical devices - Requirements for medical devices to be designated "Sterile" - Part 1: Requirements for terminally sterilised

		medical devices
24	EN 868-5: 2019	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
25	EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
26	EN ISO 11135/A1:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
27	EN ISO 17141:2020	Cleanrooms and associated controlled environments. Biocontamination control
28	EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice

2. DECLARATIONS

GENJECT hereby;

- Declared that the products meet the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.
- Declared that we will fulfil the obligations imposed by the quality system and to keep the quality system adequate and efficacious.
- Declared that we will institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred to in Annex X, and to implement appropriate means to apply any necessary corrective action. We will notify immediately UDEM (NB 2292) and Türkiye İlaç ve Tıbbi Cihaz Kurumu if any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health. We will notify immediately UDEM (NB 2292) and Türkiye İlaç ve Tıbbi Cihaz Kurumu if any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer
- Declared that the products do not contain animal origin tissues according to 2003/32/EC Directive.

- Declared that the products do not contain human blood and derivatives according to 2000/70/EC Directive.
- Declared that the products do not contain phthalates according to Regulation on Classification, Packaging and Labeling of Dangerous Substances and Preparations published in the Resmi Gazete numbered 27092 repeated.

3. PACKAGING

3.1. Example labeling and boxing

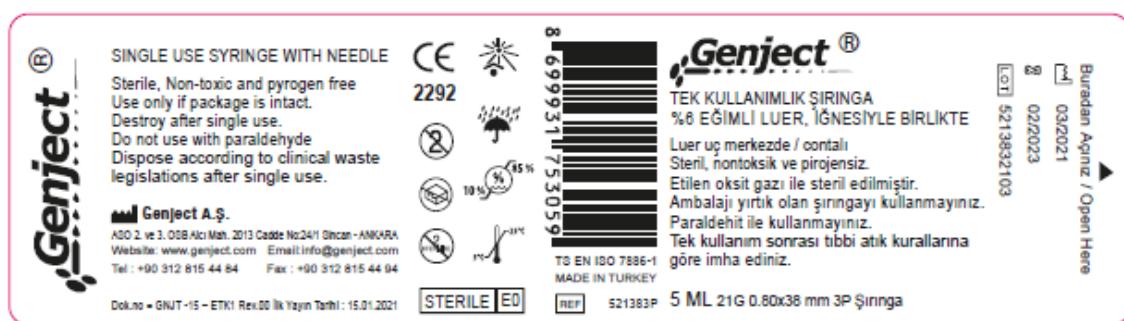


Figure 2. Example of 5 ml 21 G 38 mm Disposable Hypodermic Syringe



Figure 3. Example of 5 ml 21 G 38 mm Disposable Hypodermic Syringe Box

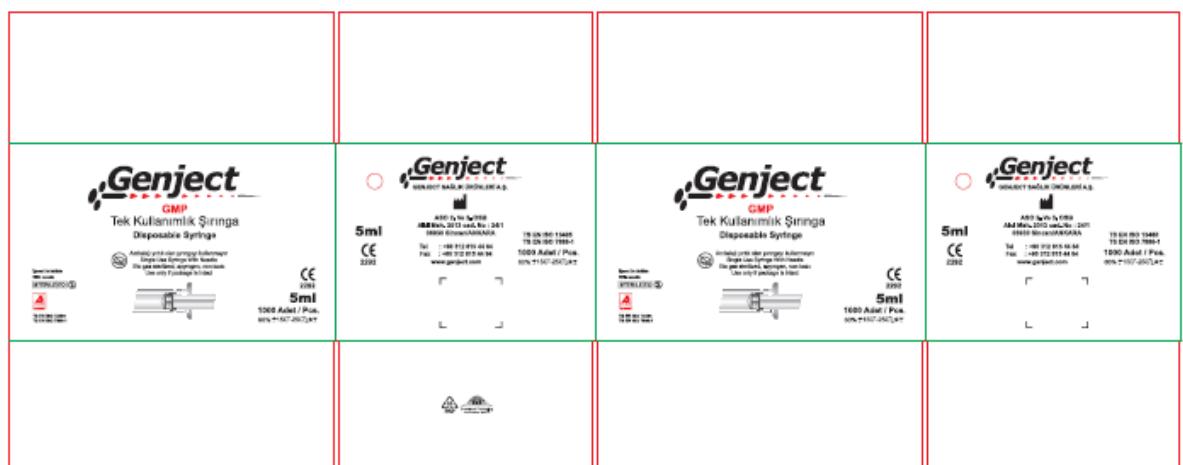


Figure 4. Example of 5 ml 21 G 38 mm Disposable Hypodermic Syringe Case

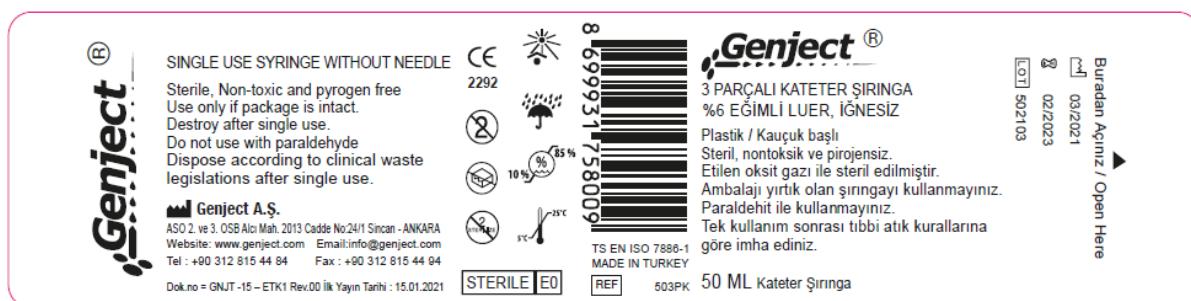


Figure 5. Example of 50 ml Catheter Syringe

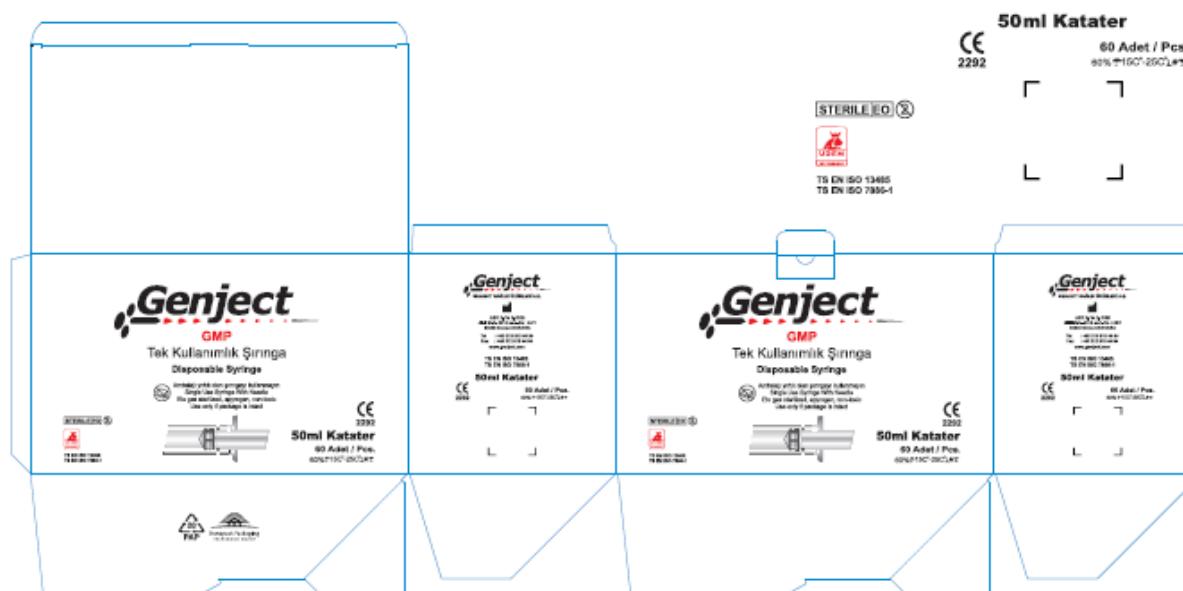


Figure 6. Example of 50 ml Catheter Syringe Box

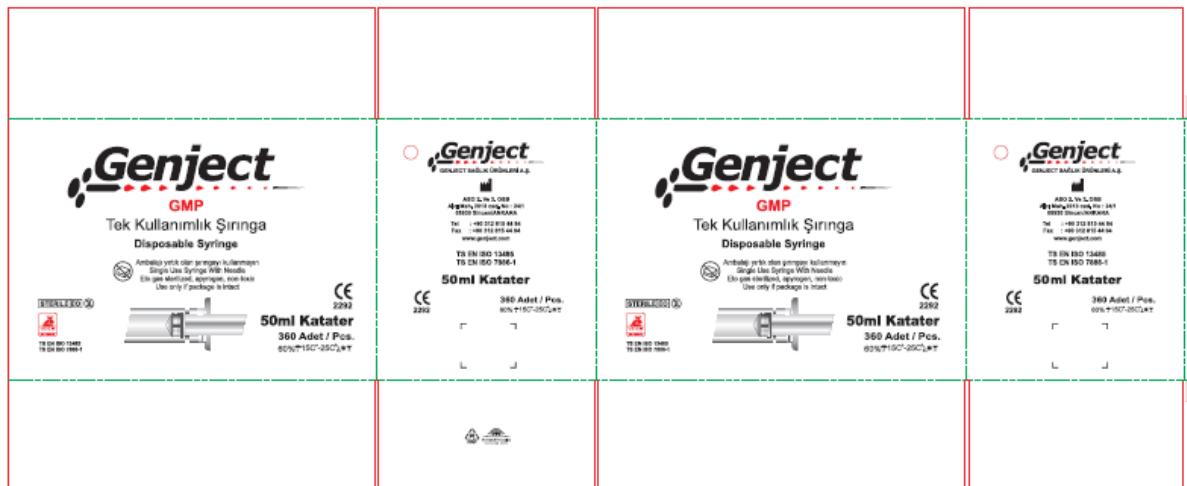


Figure 7. Example of 50 ml Catheter Syringe Case



Figure 8. Example of 21 G 38 mm Needle