

# CERTIFICATE OF REGISTRATION



*This is to Certify that the  
Medical Devices – Quality Management System  
of*

## **ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET ANONİM ŞİRKETİ**

**AKÇALAR MAH. KALE (660) CAD. NO:1 NİLÜFER / BURSA / TÜRKİYE**

**has been independently assessed and is compliant  
with the requirements of**

**ISO 13485:2016**

**This Certificate is applicable to the following product or service ranges:**

**DESIGN, PRODUCTION AND SALES OF HYPODERMIC SYRINGE  
AND NEEDLE**

**HİPODERMİK ŞİRINGA VE İĞNE TASARIMI, ÜRETİMİ VE SATIŞI**

**:: Certificate No :: TR53525H**

<b>Date of initial registration</b>	<b>19 November 2020</b>
<b>Date of this Certificate</b>	<b>19 November 2020</b>
<b>Surveillance audit on or before</b>	<b>18 November 2021</b>
<b>Recertification Due / Certificate expiry</b>	<b>18 November 2023</b>

This Certificate is remains valid subject to satisfactory surveillance audits.



*Emmanuel*

**Emmanuel ADEMOSU  
Director**

For verification and updated information concerning the present certificate visit to [http://staunchlyservices.com/search\\_certified\\_client.php](http://staunchlyservices.com/search_certified_client.php)  
This Certificate is the property of Staunchly Management & System Services Limited and shall be returned immediately when demanded

### **STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED**

Labrynth Business Centre, 43 Middle Hill Gate, Stockport,

Great Manchester, England-SK1 3DG

Web :- [www.staunchlyservices.com](http://www.staunchlyservices.com)

E-mail :- [info@staunchlyservices.com](mailto:info@staunchlyservices.com)

Phone :- +44 740 482 3687

Company Registered in England and Wales with Company Number 11488683



## EC Certificate

### Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-20-680

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

#### ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET ANONİM ŞİRKETİ

Hasanağa Osb Mah. 15. Cad. No:10 Nilüfer/ Bursa/ Turkey

**Product:** Sterile Hypodermic Syringe

**Types:**

Sterile Hypodermic Syringe with Gasket and Needle, luer lock

Sterile Hypodermic Syringe with Gasket and Needle, luer slip

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

**Report Number:** M.5591.01  
**Date of first issue:** 02 July 2020  
**Date of last issue:** 20 January 2021  
**Revision Number:** 01  
**Expiry Date:** 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhteşem Gökhan Yücel  
Head of Notified Body

20 January 2021, Istanbul, Turkey



## PRODUCT CONTENTS DECLARATION

### ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş.

**ADDRESS** : Hasanağa Osb Mah. 15. Cad. No:10 Nilüfer / BURSA  
**WAREHOUSE ADDRESS** : Hasanağa Osb Mah. 15. Cad. No:10 Nilüfer / BURSA

**Tel** : +90 224 909 13 90  
**E-mail** : info@aldarmed.com

<b>Product</b>	Sterile Hypodermic Syringe, with needle
<b>Class</b>	SFDA / MDS G5, Rule 6, Class B
<b>GMDN Codes</b>	35904 - Syringe, hypodermic, metered-delivery
<b>Brand</b>	AldarMed

ALDAR MEDİKAL IMPORT EXPORT INDUSTRY AND TRADE INC. Products listed in Annex 2,

- Human product defined in article 1 of the 2001/83/EC Regulation,
- Human blood and/or derivatives defined in Article 7.4 of Annex I of Regulation 93/42/EC (amended by regulation 2007/47/EC),
- Animal tissue covered by the 2003/83/EC Directive,
- Phthalates within the scope of Regulation 67/548/EEC,
- PFOS (perfluorooctanesulfonates) within the scope of Directive 2006/122/EC

It declares that does not contain.



## PRODUCT CONTENTS DECLARATION

### ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş.

**ADDRESS** : Hasanağa Osb Mah. 15. Cad. No:10 Nilüfer / BURSA  
**WAREHOUSE ADDRESS** : Hasanağa Osb Mah. 15. Cad. No:10 Nilüfer / BURSA

**Tel** : +90 224 909 13 90  
**E-mail** : info@aldarmed.com

**Approved Establishment** : Kiwa Belgelendirme Hizmetleri A.Ş.  
**Approved Establishment No** : 1984  
**Approved Establishment Address** : İTOSB 9. Cadde No:15 Tepeören-Tuzla-İstanbul-TURKEY  
**Certificate Number** : M.5591.01  
**Certificate Issued Date** : 02.07.2020  
**Certificate Validity Date** : 27.05.2024  
**Place, Release Date** : BURSA, 02.07.2020

**General Manager**

**Stamp / Signature / Date**

**Product List :**

Appendix 2 Product List document.

**ALDAR MEDİKAL**  
**İTH. İHR. SAN. TİC. A.Ş.**  
Hasanağa OSB Mah. 15. Cad.  
No:10 Nilüfer / BURSA  
Çekirge V.D. 050 094 59 55  
Mersis No:0050094595500001

18.08.2024



# ALDAR MEDICAL

## MEDICAL SUPPLIES FACTORY

Aldar Medical produces ***Sterile Medical Syringes ( Luer Slip)*** with the size of ***2 ml, 3 ml , 5 ml ,10 ml (21G, 22G, 23G, 25G, 26G ,27G)*** ***Hypodermic Needles*** under strict clean-room manufacturing conditions according to current GMP, ISO 7886, ISO 7864, ISO 13485 and MDR.



2 CC -2,5 CC LUER-SLIP HYPODERMIC SYRINGE



3 CC LUER-SLIP HYPODERMIC SYRINGE



5 CC LUER-SLIP HYPODERMIC SYRINGE



10 CC LUER-SLIP HYPODERMIC SYRINGE

Address : Hasanağa OSB Mah. 15. Cadde No:10 Nilüfer/Bursa

TURKEY

Phone : +90 (224) 909 13 90

Mail : [info@aldarmed.com](mailto:info@aldarmed.com)

## WE ARE EXPERT IN OUR BUSINESS!

### ABOUT US

Aldar Medikal carries out management, production, quality, R&D, marketing and logistics activities on a total area of 9200 m<sup>2</sup>, 7500 m<sup>2</sup> of which is closed. Aldar Medical produces medical disposable syringes and hypodermic needles in accordance with the latest technology in European standards.

Aldar Medikal, while maintaining the continuity of customer satisfaction by keeping the service and quality standards of the products it produces at the highest level in the health sector, which is growing day by day, closely follows the developments in the field in which it operates and meets the customer expectations and needs in the best way.

2, 2.5, 3, 5 and 10 cc disposable sterile syringes and hypodermic needles (21G – 23 G) are produced in ISO 8 class clean rooms in fully automatic production lines in accordance with cGMP and ISO 13485, ISO7886 and ISO7864, and have CE certificate. After the products are sterilized with ethylene oxide (EO), they are ventilated in special conditioning rooms for a minimum of 8 hours. It is shipped to customers after sterility and (EO) residue analysis.



## OUR QUALITY POLICY



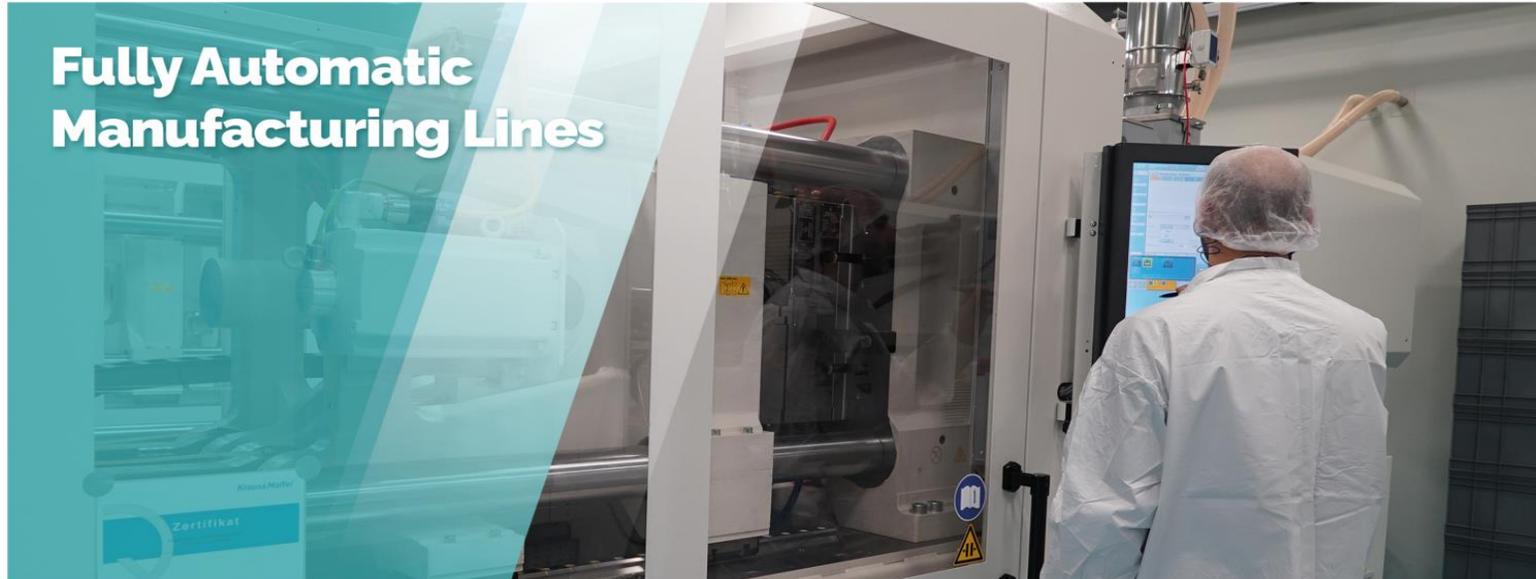
- Listening, understanding and meeting the needs and demands of our customers as fully as possible; To ensure the continuity of customer satisfaction through efforts to produce the most appropriate and most economical solutions.
- To become a leader in technology with new methods and continuous improvement approach in our fields of activity.
- With the participation of our employees, to take responsibility in accordance with the rules specified in the Quality Management System documents in honesty and trust and to ensure their active participation. To place and spread the understanding of Quality in every field.
- To make decisions for customer satisfaction, to produce services and to ensure that our processes are more efficient in stability and trust with our suppliers.
- To be an exemplary organization that respects society and the environment; To contribute to the country's economy through production and employment.

## VISION

To maintain the continuity of customer satisfaction by keeping the service and quality standards of the products we produce at the highest level in the health sector, which is growing day by day, and to be among the leading companies in the sector by closely following the developments in the field in which we operate and meeting the expectations and needs of our customers in the best way.

## MISSION

Our organization, to companies operating abroad and in various parts of our country, especially in Bursa; provides services in the supply of syringes that we have produced. With our customer-oriented, trust-based service approach and our products with certified quality standards, we produce economical solutions and meet the demands of our customers in the optimum time.



## OUR CERTIFICATES

CERTIFICATE



### EC Certificate

Production Quality Assurance System according to  
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Certificate Number: 1984-MDD-20-680

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

#### Organization:

**ALDAR MEDİKAL İTHALAT İHRACAT  
SANAYİ VE TİCARET ANONİM ŞİRKETİ**

AKÇALAR MAHALLESİ KALE (660) CADDE NO:1 NİLÜFER/ BURSA /TURKEY

Product: Sterile Hypodermic Syringe

#### Types:

Sterile Hypodermic Syringe with Gasket and Needle, luer lock  
Sterile Hypodermic Syringe with Gasket and Needle, luer slip

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5591.01

Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhtesem Gökhan Yücel  
Head of Notified Body

02 July 2020, İstanbul, Turkey

Kiwa Belgelendirme Hizmetleri A.Ş.  
İTOGB 9. Cad. No 15 Tepeören, Tuza, İstanbul, Turkey  
Tel: +90 216 583 25 75 - Fax: +90 216 583 25 74  
Web: www.kiwa.com.tr - e-mail: post@kiwa.com

**Technical Universal Verification**  
**CERTIFICATE**

This Certificate has been awarded to:  
**ALDAR MEDİKAL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş.**

**AKÇALAR MAH. KALE CAD. NO:1 NİLÜFER  
BURSA - TURKEY**

In Recognition of the Organisation's Management System which complies with:  
**ISO 13485 : 2016**  
For the Scope of Activities described below:

**HYPODERMIC SYRINGE AND NEEDLE DESIGN, PRODUCTION AND SALES**

Certificate No : 4160      Reissue Date :-  
Date of Audit : 03.09.2019      Expiry Date : 13.10.2020  
Date of Registration : 14.10.2019

**Technical Universal Verification**

This document is valid for 3 years provided that the management system is well maintained and surveillance audits are performed regularly. After performing the surveillance audits certificate will be reissued. The current status of this certificate can be viewed via [www.techcert.com.tr](http://www.techcert.com.tr) web site. This certificate is a property of Technical Universal Verification Certification and Training Services Co., Ltd. Thus, this certificate has to be returned if required by property owner. United Accreditation Foundation (UAF) is an accreditation body whose headquarters is located in the United States of America, which is a member of International Accreditation Forum (IAF).

**Technical Universal Verification  
Belgelendirme ve Eğitim Hizmetleri Ltd. Şti.**  
Macun Mahallesi Batı Bulvarı ATR İş Merkezi A Blok  
No: 1/3 Yenimahalle - ANKARA / TÜRKİYE  
Tel: 00 90 312 231 82 02  
- web: [www.techcert.com.tr](http://www.techcert.com.tr)  
- e-mail: [info@techcert.com.tr](mailto:info@techcert.com.tr)

**UAF**  
ACCREDITED FOUNDATION  
CB - MS - 0602

FR 32/24.07.2019/REV.02

◆ CERTIFICADO ◆ CERTIFICAT ◆ CERTIFICATE ◆ ЗЕРТИФИКАТ ◆ CERTIFICATE ◆ CERTIFICAT ◆ CERTIFICATE

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HİPODERMİK ŞİRINGA VE İĞNE TASARIMI, ÜRETİMİ VE SATIŞI**

:: Certificate No :: **TR53525H**

Date of initial registration	19 November 2020
Date of this Certificate	19 November 2020
Surveillance audit on or before	18 November 2021
Recertification Due / Certificate expiry	18 November 2023

This Certificate is remains valid subject to satisfactory surveillance audits.

**Emmanuel ADEMOSU**  
Director



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**STAUNCHLY MANAGEMENT AND SYSTEM SERVICES LIMITED**

Labyrinth Business Centre, 43 Middle Hill Gate, Stockport,

Great Manchester, England-SK1 3DG

Web : [www.staunchlyservices.com](http://www.staunchlyservices.com)

E-mail : [info@staunchlyservices.com](mailto:info@staunchlyservices.com)

Phone : +44 740 482 3687

Company Registered in England and Wales with Company Number 11488683



SMS/PM001/REV08

# SYRINGE

## 2 CC LUER SLIP

PRODUCT CODE	NAME OF PRODUCT	PRODUCT DESCRIPTION	NEEDLE SIZE	
152.LS0221G1.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 21Gx1"	Luer-Slip	21Gx1"	0.80 x 25 mm
152.LS0221G112.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 21Gx1½"	Luer-Slip	21Gx1½"	0.80 x 38 mm
152.LS0221G114.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 21Gx1¼"	Luer-Slip	21Gx1¼"	0.80 x 32 mm
152.LS0221G58.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 21Gx5/8	Luer-Slip	21Gx5/8	0.80 x 16 mm
152.LS0222G1.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 22Gx1"	Luer-Slip	22Gx1"	0.70 x 25 mm
152.LS0222G112.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 22Gx1½"	Luer-Slip	22Gx1½"	0.70 x 38 mm
152.LS0222G114.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 22Gx1¼"	Luer-Slip	22Gx1¼"	0.70 x 32 mm
152.LS0223G1.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 23Gx1"	Luer-Slip	23Gx1"	0.60 x 25 mm
152.LS0223G112.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 23Gx1½"	Luer-Slip	23Gx1½"	0.60 x 38 mm
152.LS0223G114.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 23Gx1¼"	Luer-Slip	23Gx1¼"	0.60 x 32 mm
152.LS0225G1.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 25Gx1"	Luer-Slip	25Gx1"	0.50 x 25 mm
152.LS0225G112.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 25Gx1½"	Luer-Slip	25Gx1½"	0.50 x 38 mm
152.LS0225G114.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 25Gx1¼"	Luer-Slip	25Gx1¼"	0.50 x 32 mm
152.LS0226G1.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 26Gx1"	Luer-Slip	26Gx1"	0.45 x 25 mm
152.LS0226G112.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 26Gx1½"	Luer-Slip	26Gx1½"	0.45 x 38 mm
152.LS0226G114.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 26Gx1¼"	Luer-Slip	26Gx1¼"	0.45 x 32 mm
152.LS0227G1.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 27Gx1"	Luer-Slip	27Gx1"	0.40 x 25 mm
152.LS0227G112.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 27Gx1½"	Luer-Slip	27Gx1½"	0.40 x 38 mm
152.LS0227G114.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 27Gx1¼"	Luer-Slip	27Gx1¼"	0.40 x 32 mm
152.LS02272.R01	Hypodermic Syringe, Seal, Needle 2 cc Luer Slip 27Gx2"	Luer-Slip	27Gx2"	0.40 x 50 mm

# SYRINGE

## 3 CC LUER SLIP

PRODUCT CODE	NAME OF PRODUCT	PRODUCT DESCRIPTION	NEEDLE SIZE	
152.LS0321G1.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 21Gx1"	Luer-Slip	21G x 1"	0.80 x 25 mm
152.LS0321G114.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 21Gx1¼"	Luer-Slip	21G x 1 1/4"	0.80 x 32 mm
152.LS0321G112.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 21Gx1½"	Luer-Slip	21G x 1 1/2"	0.80 x 38 mm
152.LS0321G58.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 21Gx5/8	Luer-Slip	21G x 5/8"	0.80 x 16 mm
152.LS0322G1.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 22Gx1"	Luer-Slip	22G x 1"	0.70 x 25 mm
152.LS0322G114.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 22Gx1¼"	Luer-Slip	22G x 1 1/4"	0.70 x 32 mm
152.LS0322G112.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 22Gx1½"	Luer-Slip	22G x 1 1/2"	0.70 x 38 mm
152.LS0323G1.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 23Gx1"	Luer-Slip	23G x 1"	0.60 x 25 mm
152.LS0323G114.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 23Gx1¼"	Luer-Slip	23G x 1 1/4"	0.60 x 32 mm
152.LS0323G112.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 23Gx1½"	Luer-Slip	23G x 1 1/2"	0.60 x 38 mm
152.LS0325G1.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 25Gx1"	Luer-Slip	25G x 1"	0.50 x 25 mm
152.LS0325G114.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 25Gx1¼"	Luer-Slip	25G x 1 1/4"	0.50 x 32 mm
152.LS0325G112.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 25Gx1½"	Luer-Slip	25G x 1 1/2"	0.50 x 38 mm
152.LS0326G1.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 26Gx1"	Luer-Slip	26G x 1"	0.45 x 25 mm
152.LS0326G114.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 26Gx1¼"	Luer-Slip	26G x 1 1/4"	0.45 x 32 mm
152.LS0326G112.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 26Gx1½"	Luer-Slip	26G x 1 1/2"	0.45 x 38 mm
152.LS0327G1.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 27Gx1"	Luer-Slip	27G x 1"	0.40 x 25 mm
152.LS0327G114.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 27Gx1¼"	Luer-Slip	27G x 1 1/4"	0.40 x 32 mm
152.LS0327G112.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 27Gx1½"	Luer-Slip	27G x 1 1/2"	0.40 x 38 mm
152.LS0327G2.R01	Hypodermic Syringe, Seal, Needle 3 cc Luer Slip 27Gx2"	Luer-Slip	27G x 2"	0.40 x 50 mm



# SYRINGE

## 5 CC LUER SLIP

PRODUCT CODE	NAME OF PRODUCT	PRODUCT DESCRIPTION	NEEDLE SIZE	
152.LS0521G1.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 21Gx1"	Luer-Slip	21G x 1"	0.80 x 25 mm
152.LS0521G114.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 21Gx1¼"	Luer-Slip	21G x 1 1/4"	0.80 x 32 mm
152.LS0521G112.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 21Gx1½"	Luer-Slip	21G x 1 1/2"	0.80 x 38 mm
152.LS0521G58.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 21Gx5/8	Luer-Slip	21G x 5/8"	0.80 x 16 mm
152.LS0522G1.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 22Gx1"	Luer-Slip	22G x 1"	0.70 x 25 mm
152.LS0522G114.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 22Gx1¼"	Luer-Slip	22G x 1 1/4"	0.70 x 32 mm
152.LS0522G112.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 22Gx1½"	Luer-Slip	22G x 1 1/2"	0.70 x 38 mm
152.LS0523G1.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 23Gx1"	Luer-Slip	23G x 1"	0.60 x 25 mm
152.LS0523G114.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 23Gx1¼"	Luer-Slip	23G x 1 1/4"	0.60 x 32 mm
152.LS0523G112.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 23Gx1½"	Luer-Slip	23G x 1 1/2"	0.60 x 38 mm
152.LS0525G1.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 25Gx1"	Luer-Slip	25G x 1"	0.50 x 25 mm
152.LS0525G114.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 25Gx1¼"	Luer-Slip	25G x 1 1/4"	0.50 x 32 mm
152.LS0525G112.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 25Gx1½"	Luer-Slip	25G x 1 1/2"	0.50 x 38 mm
152.LS0526G1.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 26Gx1"	Luer-Slip	26G x 1"	0.45 x 25 mm
152.LS0526G114.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 26Gx1¼"	Luer-Slip	26G x 1 1/4"	0.45 x 32 mm
152.LS0526G112.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 26Gx1½"	Luer-Slip	26G x 1 1/2"	0.45 x 38 mm
152.LS0527G1.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 27Gx1"	Luer-Slip	27G x 1"	0.40 x 25 mm
152.LS0527G114.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 27Gx1¼"	Luer-Slip	27G x 1 1/4"	0.40 x 32 mm
152.LS0527G112.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 27Gx1½"	Luer-Slip	27G x 1 1/2"	0.40 x 38 mm
152.LS0527G2.R01	Hypodermic Syringe, Seal, Needle 5 cc Luer Slip 27Gx2"	Luer-Slip	27G x 2"	0.40 x 50 mm

# SYRINGE

## 10 CC LUER SLIP

PRODUCT CODE	NAME OF PRODUCT	PRODUCT DESCRIPTION	NEEDLE SIZE	
152.LS1021G1.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 21Gx1"	Luer-Slip	21G x 1"	0.80 x 25 mm
152.LS1021G114.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 21Gx1¼"	Luer-Slip	21G x 1 1/4"	0.80 x 32 mm
152.LS1021G112.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 21Gx1½"	Luer-Slip	21G x 1 1/2"	0.80 x 38 mm
152.LS1021G58.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 21Gx5/8	Luer-Slip	21G x 5/8"	0.80 x 16 mm
152.LS1022G1.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 22Gx1"	Luer-Slip	22G x 1"	0.70 x 25 mm
152.LS1022G114.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 22Gx1¼"	Luer-Slip	22G x 1 1/4"	0.70 x 32 mm
152.LS1022G112.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 22Gx1½"	Luer-Slip	22G x 1 1/2"	0.70 x 38 mm
152.LS1023G1.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 23Gx1"	Luer-Slip	23G x 1"	0.60 x 25 mm
152.LS1023G114.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 23Gx1¼"	Luer-Slip	23G x 1 1/4"	0.60 x 32 mm
152.LS1023G112.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 23Gx1½"	Luer-Slip	23G x 1 1/2"	0.60 x 38 mm
152.LS1025G1.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 25Gx1"	Luer-Slip	25G x 1"	0.50 x 25 mm
152.LS1025G114.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 25Gx1¼"	Luer-Slip	25G x 1 1/4"	0.50 x 32 mm
152.LS1025G112.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 25Gx1½"	Luer-Slip	25G x 1 1/2"	0.50 x 38 mm
152.LS1026G1.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 26Gx1"	Luer-Slip	26G x 1"	0.45 x 25 mm
152.LS1026G114.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 26Gx1¼"	Luer-Slip	26G x 1 1/4"	0.45 x 32 mm
152.LS1026G112.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 26Gx1½"	Luer-Slip	26G x 1 1/2"	0.45 x 38 mm
152.LS1027G1.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 27Gx1"	Luer-Slip	27G x 1"	0.40 x 25 mm
152.LS1027G114.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 27Gx1¼"	Luer-Slip	27G x 1 1/4"	0.40 x 32 mm
152.LS1027G112.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 27Gx1½"	Luer-Slip	27G x 1 1/2"	0.40 x 38 mm
152.LS1027G2.R01	Hypodermic Syringe, Seal, Needle 10 cc Luer Slip 27Gx2"	Luer-Slip	27G x 2"	0.40 x 50 mm

## PRODUCTION



## TECHNICAL DATA SHEET OF 2 ML SYRINGE

**Syringe:** Made of medical plastic materials, sterile containing synthetic rubber, single use

**Barrel:** Polypropylene (Medical Grade)  
(Random Copolymer)

**Plunger:** Polyethylene (Medical Grade)  
(Natural HD Polyethylene)

**Gasket:** Isoprene (Natural Rubber)  
Lubricant: Silicone oil (Medical Grade)

**Lubricant:** Silicone oil (Medical Grade),

**Hypodermic needle:** Sterile, single use. AISI 316 quality stainless steel (Stainless Steel SUS-304). Used with syringes.

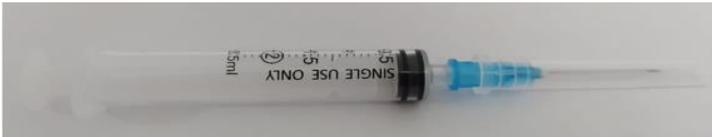


### Hypodermic syringe and needle models;

Product Name	Size	Needle Sizes
Hypodermic syringe, with gasket, with needle, Luer Slip	2 mL	21Gx1"
		21Gx1¼"
		21Gx1½"
		22Gx1"
		22Gx1¼"
		22Gx1½"
		23Gx1"
		23Gx1¼"
		23x1½"
		24Gx1"
		24Gx1¼"
		24x1½"

Dead Spaces:

Syringe size:	2 mL
Dead spaces:	<0,07 mL



Our product doesn't include human blood derivatives, human blood, blood products, human-derived plasma or blood cells, human cell, tissue, transplant organs or products made from them, biocidal products, inanimate animal tissues and products made from non-living animal tissues, animal origin tissue and cells, drugs, herbal or medicinal products, latex and phthalates.

Nontoxic, nonpyrogenic.

**Sterilization:** Sterilized with ethylene oxide. It complies with EN ISO 11135-1 standards.

**Packaging:** Suitable for ethylene oxide sterilization and medical device use



**Shelf life:** It is stored at room temperature. It should be kept away from sunlight and moisture.

**Classification:** IIa (Medical Device Directive 93/42/EEC)

**Biocompatibility:** External communicator / blood conduit, indirect, A-limited contact,  $\leq 24$  s (10993-1 Table A.1)

GMDN Codes: 35904 - Syringe, Hypodermic, measured distribution 59230 – Hypodermic needle, single use, sterile  
ISO 13485:2016 CE

## TECHNICAL DATA SHEET OF 3 ML SYRINGE

**Syringe:** Made of medical plastic materials, sterile containing synthetic rubber, single use

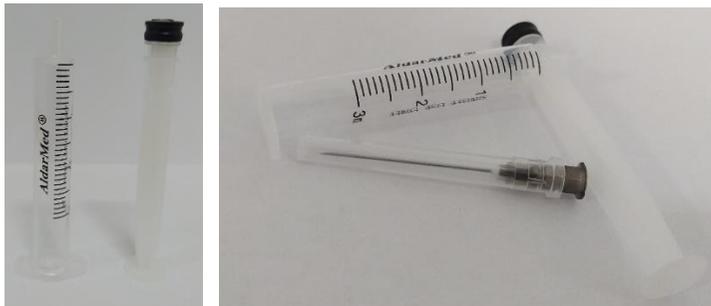
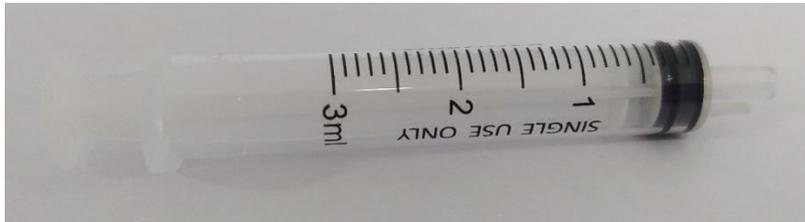
**Barrel:** Polypropylene (Medical Grade), (Random Copolymer)

**Plunger:** Polyethylene (Medical Grade) (Natural HD Polyethylene)

**Gasket:** Isoprene (Natural Rubber)

**Lubricant:** Silicone oil (Medical Grade), <0,25 mg/cm<sup>2</sup>

**Hypodermic needle:** Sterile, single use. AISI 316 quality stainless steel (Stainless Steel SUS-304). Used with syringes.



### Hypodermic syringe and needle models;

Product Name	Size	Needle Sizes
Hypodermic syringe, with gasket, with needle, Luer Slip	3 ml	21Gx1" 21Gx1¼" 21Gx1½" 22Gx1" 22Gx1¼" 22Gx1½" 23Gx1" 23Gx1¼" 23x1½" 24Gx1" 24Gx1¼" 24x1½"

Dead Spaces:

Syringe size:	3mL
Dead spaces:	0,07 mL

Our product doesn't include human blood derivatives, human blood, blood products, human-derived plasma or blood cells, human cell, tissue, transplant organs or products made from them, biocidal products, inanimate animal tissues and products made from non-living animal tissues, animal origin tissue and cells, drugs, herbal or medicinal products, latex and phthalates.

Nontoxic, nonpyrogenic.

**Sterilization:** Sterilized with ethylene oxide. It complies with EN ISO 11135-1 standards.

**Packaging:** Suitable for ethylene oxide sterilization and medical device use



**Shelf life:** It is stored at room temperature. It should be kept away from sunlight and moisture.

**Classification:** IIa (Medical Device Directive 93/42/EEC)

**Biocompatibility:** External communicator / blood conduit, indirect, A-limited contact, ≤24 s (10993-1 Table A.1)

GMDN Codes: 35904 - Syringe, Hypodermic, measured distribution 59230 – Hypodermic needle, single use, sterile

ISO 13485:2016 CE

## TECHNICAL DATA SHEET OF 5 ML SYRINGE

**Syringe:** Made of medical plastic materials, sterile containing synthetic rubber, single use

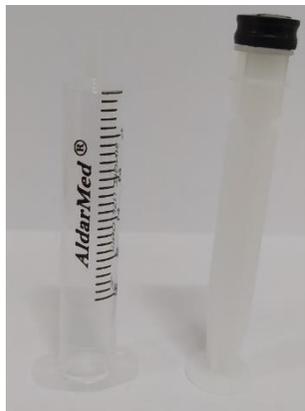
**Barrel:** Polypropylene (Medical Grade), (Random Copolymer)

**Plunger:** Polyethylene (Medical Grade) (Natural HD Polyethylene)

**Gasket:** Isoprene (Natural Rubber)

**Lubricant:** Silicone oil (Medical Grade), <0,25 mg/cm<sup>2</sup>

**Hypodermic needle:** Sterile, single use. AISI 316 quality stainless steel (Stainless Steel SUS-304). Used with syringes.



### Hypodermic syringe and needle models;

Product Name	Size	Needle Sizes
Hypodermic syringe, with gasket, with needle, <u>Luer Slip</u>	5 mL	21Gx1" 21Gx1¼" 21Gx1½" 22Gx1" 22Gx1¼" 22Gx1½" 23Gx1" 23Gx1¼" 23x1½" 24Gx1" 24Gx1¼" 24x1½"

### Dead Spaces:

Syringe size:	5 mL
Dead spaces:	0,075 mL

Our product doesn't include human blood derivatives, human blood, blood products, human-derived plasma or blood cells, human cell, tissue, transplant organs or products made from them, biocidal products, inanimate animal tissues and products made from non-living animal tissues, animal origin tissue and cells, drugs, herbal or medicinal products, latex and phthalates.

Nontoxic, nonpyrogenic.

**Sterilization:** Sterilized with ethylene oxide. It complies with EN ISO 11135-1 standards.

**Packaging:** Suitable for ethylene oxide sterilization and medical device use



**Shelf life:** It is stored at room temperature. It should be kept away from sunlight and moisture.

**Classification:** IIa (Medical Device Directive 93/42/EEC)

**Biocompatibility:** External communicator / blood conduit, indirect, A-limited contact, ≤24 s (10993-1 Table A.1)

**GMDN Codes:** 35904 - Syringe, Hypodermic, measured distribution 59230 – Hypodermic needle, single use, sterile

ISO 13485:2016 C

## TECHNICAL DATA SHEET OF 10 ML SYRINGE

**Syringe:** Made of medical plastic materials, sterile containing synthetic rubber, single use

**Barrel:** Polypropylene (Medical Grade), (Random Copolymer)

**Plunger:** Polyethylene (Medical Grade) (Natural HD Polyethylene)

**Gasket:** Isoprene (Natural Rubber)

**Lubricant:** Silicone oil (Medical Grade), <0,25 mg/cm<sup>2</sup>

**Hypodermic needle:** Sterile, single use. AISI 316 quality stainless steel (Stainless Steel SUS-304). Used with syringes.



Hypodermic syringe and needle models;

Product Name	Size	Needle Sizes
Hypodermic syringe, with gasket, with needle, <u>Luer Slip</u>	10 mL	21Gx1"
		21Gx1¼"
		21Gx1½"
		22Gx1"
		22Gx1¼"
		22Gx1½"
		23Gx1"
		23Gx1¼"
		23x1½"
		24Gx1"
		24Gx1¼"
		24x1½"

Dead Spaces:

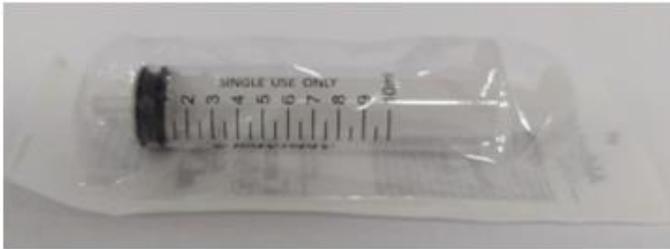
Syringe size:	10 mL
Dead spaces:	0,10 mL

Our product doesn't include human blood derivatives, human blood, blood products, human-derived plasma or blood cells, human cell, tissue, transplant organs or products made from them, biocidal products, inanimate animal tissues and products made from non-living animal tissues, animal origin tissue and cells, drugs, herbal or medicinal products, latex and phthalates.

Nontoxic, nonpyrogenic.

**Sterilization:** Sterilized with ethylene oxide. It complies with EN ISO 11135-1 standards.

**Packaging:** Suitable for ethylene oxide sterilization and medical device use



**Shelf life:** It is stored at room temperature. It should be kept away from sunlight and moisture.

**Classification:** IIa (Medical Device Directive 93/42/EEC)

**Biocompatibility:** External communicator / blood conduit, indirect, A-limited contact,  $\leq 24$  s (10993-1 Table A.1)

GMDN Codes: 35904 - Syringe, Hypodermic, measured distribution 59230 - Hypodermic needle, single use, sterile

ISO 13485:2016 CE