

17/05/2024

MANUFACTURER'S DECLARATION

Regarding Regulation (EU) No 2023/607 amending Regulation (EU) No 2017/745 on transitional provisions for medical devices:

As a manufacturer of medical devices subject to the certificate numbered M.2016.106.6922 specified in the table below within the scope of Council Directive 93/42/EEC (MDD) on Medical Devices

Manufacturer name	Ayset Tıbbi Ürünler Ve Plastik Tekstil Elektronik Gıda Temizlik Maddeleri İnşaat Müteahhitlik San. A.Ş.
Manufacturer address and contact information	Sarıhamzalı Mahallesi 47007 Sokak No:36/A Seyhan Adana TURKEY Phone: +90 322 441 12 99 Fax: +90 322 441 12 98 Web: www.ayset.com E-mail: info@ayset.com
Individual Identification Number-SRN (if available)	TR-MF-000016409

Name of Authorized Representative (if applicable)	Not applicable
Address and contact information of the Authorized Representative	Not applicable
Individual Identification Number-SRN	Not applicable

Name of notified body (if any)	Udem Uluslararası Belgelendirme Denetim Eğitim Merkezi Sanayi Ve Ticaret Anonim Şirketi
Identification number of the notified body (if available)	2292
Directive Certificate number(s) under which this approval was made (if any)	M.2016.106.6922
Original expiration date (if any) stated in the Directive Certificate before extension of validity	27 May 2024
Extended validity/transitional period end date	31 December 2028
Contract Number and contract date with the Notified Body	CNT_UDEM.0330/P1/R0 13 May 2024
Devices within the Scope of Application	Sterile, Disposable 3-Piece Blood Gas Syringe with Needle Sterile, Disposable 3-Piece Syringes (Without Needle, Luer Slip/ Luer Lock) Sterile, Disposable 2-Piece Syringes (Without Needle, Luer Slip/ Luer Lock) Sterile, Disposable 3-Piece Syringes (With Needle, Luer Slip/ Luer Lock)

	Sterile, Disposable 2-Piece Syringes (With Needle, Luer Slip/ Luer Lock)
	Sterile, Disposable U-100 Insulin Syringe (Without Needle)
	Sterile, Disposable U-100 Insulin Syringe (With Needle)
	Sterile, Disposable Tuberculin Syringe (Without Needle)
	Sterile, Disposable Tuberculin Syringe (With Needle)
	Sterile, Disposable Hypodermic Needles
	Sterile, Disposable Vacuum Blood Collection Needles
	Sterile, Disposable Vacuum Blood Collection Needle Butterfly Set Type
	Sterile, Disposable Insulin Pen Injector Needles

Related devices; We continue to comply with Council Directive 93/42/EEC,

Related devices; There is no significant change in its design and intended use,

Related devices; does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other matters relevant to the protection of public health,

As the manufacturer of the relevant devices, we have implemented a quality management system (QMS) in our company in accordance with MDR Article 10(9) before May 26, 2024,

As the manufacturer of the relevant devices, it is bound to the notified body of Udem International Certification Audit Training Center Industry and Trade Joint Stock Company (Approved Body Identifier Number: 2292) in accordance with the first subparagraph of Article 4.3 of MDR Annex VII before 26 May 2024, with our certificate numbered M.2016.106.6922. We declare that an official application has been made for medical devices and an MDR certification agreement numbered CNT_UDEM.0330/P1/R0 has been signed with the Notified Body on 13 May 2024.

Özgül UYAN

Chemistry

Legislative Compliance Responsible

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