EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

(EU) 2017/745 Medical Device Regulation Annex IX

Chapter I and III

Certificate Number: MDR.2292-2026/0046

Manufacturer Name	: Mitos Medikal Teknolojiler San. ve Tic. A.Ş.
Manufacturer Address	: Reşitpaşa Mah. Katar Cad. İtü Arı 1 Teknokent Binası No: 2/5 İç Kapı No:17 Sarıyer İSTANBUL / TÜRKİYE
Single Registration Number-SRN	: TR-MF-000049783
Authorized Representative Name (If any)	: Not Applicable.
Authorized Representative Address	: Not Applicable.
Device/Device Group Name **Detailed information is in the attached device list.*	: S.A.F.E Microwave Breast Cancer Screening and Diagnosis System

Based on the conformity assessment of the quality management system of the above-mentioned manufacturer according to Annex IX Chapter I and Chapter III of (EU) 2017/745 Medical Device Regulation, UDEM A.Ş. declares that the relevant requirements are met for the products listed in this certificate

The manufacturer has established, documented and implemented a quality management system that is subject to periodic surveillance assessments by UDEM A.Ş. in accordance with Annex IX Chapter I Section 3 of the related regulation.

All relevant reports starting with the number UDEM.0723 of the customer organization referred to below summarize the outcome of the assessments/reviews and refer to the relevant common specifications, if any, harmonized standards and test reports. Upon request, these reports are available in UDEM A.Ş. records in accordance with Section 10 of Chapter II of Annex XII of the MDR. For Class III and certain Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of (EU) 2017/745 Medical Device Regulation covered by this certification, an EU Technical Documentation Assessment Certificate is required before they can be placed on the market.

Customer Number	: UDEM.0723
Issue Date	: 24.07.2026
Revision Date/No	: - / -
Validity Date	: 23.07.2031
Previous Certificate(s) No., if any	: Not Applicable.

UDEM APPROVED 2292

General Manager
Stamp - Signature

UDEM A.Ş. is a Notified Body under the (EU) 2017/745 Medical Device Regulation. Notified Body No: 2292

Mutlukent Mah. 2073. Sok. (Eski 93 Sokak) No:10 Ümitköy /ANKARA
0 312 443 03 90
udem@udem.com.tr
www.udem.com.tr

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ANNEX: DEVICE LIST WITHIN THE SCOPE OF THE CERTIFICATE

DEVICE PRODUCT/DEVICE GROUP	RISK CLASS	EMDN CODE	INTENDED USE *Should be specified only for class IIb and class III devices.*
S.A.F.E Microwave Breast Cancer Screening and Diagnosis System	IIa	Z11031101	-

**Limitations on the conditions of the certificate: Not Applicable.*

CERTIFICATE HISTORY		
Rev. No.	**Rev. Date**	**Revision Explained**
00	24.07.2026	Initial Certification

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