

EU QUALITY ASSURANCE CERTIFICATE

According to Annex XI-Part A of the Regulation (EU) 2017/745 on Medical Devices

Certificate No.: 2975-MED-2501601

Manufacturer: SENPA PLASTİK SANAYİ VE TİCARET ANONİM ŞİRKETİ
Yeşilce Mah. Çelik Cad. No:61/2 Seyrantepe Kağıthane, İstanbul,
Türkiye

Manufacturer's SRN: TR-MF-000034359

Device Information: See Section 2

Report No.: MD0008-P001-R01

Specific Conditions or Limitations: N/A

Revision History: See Section 3

SZUTEST Konformitätsbewertungsstelle GmbH, Notified Body 2975, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex XI Part A, Section 6 of the Regulation (EU) 2017/745 on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Regulation. The approved quality system is subject to surveillance pursuant to Annex XI Part A Section 7 of the Regulation and unannounced site audits.

The Report, numbered above, summarizes the result of the conformity assessment and includes references to the relevant GS, harmonized standards sampled/reviewed technical documentation and test reports.

SZUTEST Konformitätsbewertungsstelle GmbH must be informed of any substantial changes in the design and/or construction of the mentioned device(s).

First Issue Date: 16-01-2025
Revision Date: 16-01-2025
Revision No.: 00
Validity Date: 15-01-2030



Benannt durch/Designated by
Zentrale der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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Mehmet İŞIKLAR
General Manager

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Section 2 – Device Information

No	Device(s)/Device Group(s)	Basic UDI-DI	Risk Class
1	Medicine Cup Reusable (Medicine Cup, Spoon, and Syringe)	Cup: 8682678537KDHNF Spoon: 8682678537KSKQ2 Syringe: 8682678537SRNRD	Im The scope of certification is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

Section 3 – Revision History

Revision No	Revision Date	Identification of changes / definitions
00	16-01-2025	Initial Certification.