**NOTIFIED BODY CONFIRMATION LETTER**
**No: MD0045-CL-01**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 and implementing Regulation (EU) 2023/1194 amending implementing Regulation (EU) 2022/2346 as regards the transitional provisions for certain medical devices.**

This letter confirms that **SZUTEST Konformitätsbewertungsstelle GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2975** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

| | |
|---|---|
| **Company Name** | R Vent Medikal Üretim A.Ş. |
| **Address** | Yazıbaşı Mah. Balkan Cad. İztıpsan Apt. No:33/1 Torbalı, İzmir, TÜRKİYE |
| **SRN Number (if available)** | TR-MF-000028282 |

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded, and for which the SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but SZUTEST Konformitätsbewertungsstelle GmbH has not yet taken responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance with the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR
- 31 December 2028 for Annex XVI products which do not require a clinical investigation.
- 31 December 2029 for Annex XVI products which require a clinical investigation.

On behalf of SZUTEST Konformitätsbewertungsstelle GmbH,

MEHMET IŞIKLAR
General Manager

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Konformitätsbewertungsstelle GmbH
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**SZUTEST Konformitätsbewertungsstelle GmbH-NB 2975**
**Friedrich-Ebert-Anlage 36 D-60325 Frankfurt am Main /GERMAN**

To check the validity of this confirmation letter please scan the barcode. To manually check, go to https://public.szutest-germany.de/ use the first 3 digits of the manufacturer name and confirmation letter No. For further information please contact md_confirmation@szutest-germany.de

**Table 1: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (Under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD device | MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| *N/A* | *N/A* | *N/A* | N/A |

**Table 2: Devices covered by this letter and for which SZUTEST Konformitätsbewertungsstelle GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (Under MDR application) | MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage) | If the MDR device is a substitute device, identification of the corresponding MDD device | MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| Sterile and Non-Sterile Breathing Circuit Systems | Class IIa | Same | Certificate #1; 2195-MED-1816401<br>Revision No:2<br>Revision Date: 26.06.2020<br>Issue Date:13.06.2018<br>Expiry Date:26.05.2024<br>NB2195: Szutest Uygunluk Değerlendirme A.Ş. |
| Sterile and Non-Sterile Breathing Filters | Class IIa | Same | Certificate #1; 2195-MED-1816401<br>Revision No:2<br>Revision Date: 26.06.2020<br>Issue Date:13.06.2018<br>Expiry Date:26.05.2024<br>NB2195: Szutest Uygunluk Değerlendirme A.Ş. |
| Sterile and Non-Sterile Catheter Mounts | Class IIa | Same | Certificate #1; 2195-MED-1816401<br>Revision No:2<br>Revision Date: 26.06.2020<br>Issue Date:13.06.2018<br>Expiry Date:26.05.2024<br>NB2195: Szutest Uygunluk Değerlendirme A.Ş. |
| Non-sterile Masks, BVM (Resuscitator) | Class IIa | Same | Certificate #1; 2195-MED-1816401<br>Revision No:2<br>Revision Date: 26.06.2020<br>Issue Date:13.06.2018<br>Expiry Date:26.05.2024<br>NB2195: Szutest Uygunluk Değerlendirme A.Ş. |
| Sterile Closed Suction System | Class IIa | Same | Certificate #1; 2195-MED-1816401<br>Revision No:2<br>Revision Date: 26.06.2020<br>Issue Date:13.06.2018<br>Expiry Date:26.05.2024<br>NB2195: Szutest Uygunluk Değerlendirme A.Ş. |

**Confirmation Letter Revision History**

| Date | Version of the letter | Action |
|---|---|---|
| 2024/04/03 | MD0045-CL-01 | Initial issue |
| 2024/09/25 | MD0045-CL-01 | O2 & Aerosol Therapy Set were removed from the list. |

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