



**UDEM Adriatic d.o.o.**  
Radnička cesta 54/R3  
10000 Zagreb, CROATIA

2023/11/10

**Simeks Tibbi Urunler San. ve Tic. Ltd. Sti**  
**Istanbul Endustri ve Ticaret Serbest Bölgesi**  
**Aydınlı SB Mah. 10. Sok**  
**No:5 Tuzla 34953**  
**Istanbul /Türkiye**

**NOTIFIED BODY CONFIRMATION LETTER**

**Reference: 2023.MDR.1673.NBCL.0036**

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 Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2022/09/06) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2022/09/06) with the following manufacturer:

**SIMEKS TIBBI URUNLER SAN. VE TIC. LTD. STI**  
**Istanbul Endustri ve Ticaret Serbest Bölgesi**  
**Aydınlı SB Mah. 10. Sok**  
**No:5 Tuzla 34953**  
**Istanbul /Türkiye**  
**SRN Number (if available): TR-MF-000015871**

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 UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but UDEM Adriatic d.o.o. has not yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

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In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 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 (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ

General Manager

  
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**Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)**

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 UDEM Adriatic d.o.o. is NOT responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)**

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
Simpass Plus PTCA Balloon Dilatation Catheter	Class III	N/A	<p><b>Certificate 1:</b> Full Quality Assurance System Certificate No: M.2019.106.12334</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p><b>Certificate 2:</b> EC Design-Examination Certificate No: M.2019.106.12334-1</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
Simpass CTO PTCA Balloon Dilatation Catheter	Class III	N/A	<p><b>Certificate 1:</b> Full Quality Assurance System Certificate No: M.2019.106.12334</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>

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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
			<p><b>Certificate 2:</b> EC Design-Examination Certificate No: M.2019.106.12334-1</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
Simpass NC/HP PTCA Balloon Dilatation Catheter	Class III	N/A	<p><b>Certificate 1:</b> Full Quality Assurance Sytem Certificate No: M.2019.106.12334</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p><b>Certificate 2:</b> EC Design-Examination Certificate No: M.2019.106.12334-1</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
SimValve Force PTV Balloon Catheter	Class III	N/A	<p><b>Certificate 1:</b> Full Quality Assurance Sytem Certificate No: M.2019.106.12884</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p><b>Certificate 2:</b> EC Design-Examination Certificate No: M.2019.106.12884 -1</p> <p>UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>

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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
SimValve Flex PTV Balloon Catheter	Class III	N/A	<p><b>Certificate 1:</b> Full Quality Assurance Sytem Certificate No: M.2019.106.12884</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p> <p><b>Certificate 2:</b> EC Design-Examination Certificate No: M.2019.106.12884 -1</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
Simpass Endo 0.014" RX PTA Balloon Dilatation Catheter	Class IIa	N/A	<p><b>Certificate 1:</b> Full Quality Assurance Sytem Certificate No: M.2020.106.13299</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
Simpass Endo 0.018" PTA OTW Balloon Dilatation Catheter	Class IIa	N/A	<p><b>Certificate 1:</b> Full Quality Assurance Sytem Certificate No: M.2020.106.13299</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>
Simpass Endo 0.035" PTA OTW Balloon Dilatation Catheter	Class IIa	N/A	<p><b>Certificate 1:</b> Full Quality Assurance Sytem Certificate No: M.2020.106.13299</p> <p>UDEM Uluslararası Belgelendirme Denetim Egitim Merkezi San. ve Tic. A.Ş. (NB2292)</p>

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### Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/11/10	2023.MDR.1673.NBCL.0036	Initial issue

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