POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 19.09.2024

BM.433.0056.2019/KW/MV/2024/0529

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificate No. 1434-IVDD-434/2019** issued for the in vitro diagnostic medical devices whose manufacturer is TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificate, was signed with **Notified Body DEKRA Certification B.V. (NB 0344)**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificate No. 1434-IVDD-434/2019 remains valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device Certification Department

Digitally signed by Poiata Vitalie
Date: 2024.11.08 16:50:50 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw
Tel.: +48 22 46 45 200
pcbc@pcbc.gov.pl

NIP 9512063356
REGON 015276609
KRS 0000144813

Initial capital
16.000.000 PLN
(fully paid)

Bank account: Bank Pekao S.A.
PL 90 1240 6003 1111 0000 4946 7594

The company registered in the District Court for
the Capital City of Warsaw, XIIIth Commercial Division

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 19.09.2024

BM.433.0056.2019/KW/MV/2024/0530

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificate No. 1434-IVDD-435/2019** issued for the in vitro diagnostic medical devices whose manufacturer is TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificate, was signed with **Notified Body DEKRA Certification B.V. (NB 0344)**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificate No. 1434-IVDD-435/2019 remains valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device Certification Department

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 19.09.2024

BM.433.0057.2019/KW/MV/2024/0524

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificate No. 1434-IVDD-436/2019** issued for the in vitro diagnostic medical devices whose manufacturer is TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificate, was signed with **Notified Body DEKRA Certification B.V. (NB 0344)**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificate No. 1434-IVDD-436/2019 remains valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device Certification Department

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 19.09.2024

BM.433.0057.2019/KW/MV/2024/0525

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificate No. 1434-IVDD-437/2019** issued for the in vitro diagnostic medical devices whose manufacturer is TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificate, was signed with **Notified Body DEKRA Certification B.V. (NB 0344)**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificate No. 1434-IVDD-437/2019 remains valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device
Certification Department

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 19.09.2024

BM.433.0058.2019/KW/MV/2024/0522

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificate No. 1434-IVDD-430/2019** issued for the in vitro diagnostic medical devices whose manufacturer is TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificate, was signed with **Notified Body DEKRA Certification B.V. (NB 0344)**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificate No. 1434-IVDD-430/2019 remains valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device Certification Department

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 19.09.2024

BM.433.0058.2019/KW/MV/2024/0523

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificate No. 1434-IVDD-431/2019** issued for the in vitro diagnostic medical devices whose manufacturer is TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificate, was signed with **Notified Body DEKRA Certification B.V. (NB 0344)**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificate No. 1434-IVDD-431/2019 remains valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device Certification Department

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 19.09.2024

BM.433.0059.2019/KW/MV/2024/0520

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificate No. 1434-IVDD-432/2019** issued for the in vitro diagnostic medical devices whose manufacturer is TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificate, was signed with **Notified Body DEKRA Certification B.V. (NB 0344)**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificate No. 1434-IVDD-432/2019 remains valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device Certification Department

POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

Warsaw, 19.09.2024

BM.433.0059.2019/KW/MV/2024/0521

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificate No. 1434-IVDD-433/2019** issued for the in vitro diagnostic medical devices whose manufacturer is TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificate, was signed with **Notified Body DEKRA Certification B.V. (NB 0344)**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2024/1860 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificate No. 1434-IVDD-433/2019 remains valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device Certification Department