CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft. – NB 2409
H-2092 Budakeszi, Erdő utca 101.

19 September 2023

Notified Body Confirmation Letter

Reference: K-2023/113

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, CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2409 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:

KEROX Ipari és Kereskedelmi Kft.
Kerox u. 1.
2038 Sóskút
Hungary

SRN Number (if available): HU-MF-000031741

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 NB 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 the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided

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Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

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 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 the Notified Body,

Valter PAPP, dr.

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Table 1: Devices covered by this letter and for which the NB 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device 1 **KEROX ZIRCOSTAR High Strength (HS) Cirkónium dioxid tömb** 5996612CSD0000UD 5996612CSS0000ZJ **KEROX ZIRCOSTAR High Translucent (HT) Cirkónium dioxid tömb**	Class IIa, rule 8	N/A	144870-19-03-30 NB 2409

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NB ID number: 2409

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
5996612CTD0000US 5996612CTS000022 **KEROX ZIRCOSTAR Ultra High Translucent (UHT) Cirkónium dioxid tömb** **5996612CUD0000V7** 5996612CUS00002F **KEROX ZIRCOSTAR High Translucent Multilayer (HTML) Cirkónium dioxid tömb** **5996612C1A0000DX** 5996612C1D0000EY **KEROX ZIRCOSTAR Ultra High Translucent Multilayer (UTML) Cirkónium dioxid tömb** 5996612C2A0000EC 5996612C2D0000FD **KEROX ZIRCOSTAR 3DML Szín- és transzlucencia-átmenetes ("háromdimenziós") cirkónium dioxid tömb** 5996612C3S0000LX			
Device 2 **KEROX-Farben színező folyadék** 5996612EFA0000P5 **KEROX -Effekten színező folyadék** 5996612EEF0000QF	Class IIa, rule 8	N/A	144977-20-02-17 NB 2409
Device 3			
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

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NB ID number: 2409

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
19-09-2023	K-2023/113	Initial issue

CE Certiso Kft.
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NB ID number: 2409

144870-19-03-30

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Kft. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

KEROX Ipari és Kereskedelmi Kft.

Headquarters: **2038. Sóskút, Kerox u. 1., Hungary**

Scope:

Pre-sintered zirconium-dioxide blank for dental prosthetics

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Pre-sintered zirconium-dioxide blank	KEROX ZIRCOSTAR	Prosthetics (crown, inlay, onlay, bridge)	HS: High Strength, HT: High Translucent, UHT: Ultra High Translucent, HTML: High Translucent Multilayer, UTML: Ultra High Translucent Multilayer 3DML: Multilayer, Multitranslucent	IIa

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 180-CE-180912

Issue: 3
Issued: 16 April 2021
First issued: 30 March 2019
Start date of certified status: 30 March 2019

Expires:
29 March 2024

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Valter PAPP, Dr.
General Manager

CE Certiso Ltd. NB2409 Notified Body

CE Certiso Kft.
H-2092 Budakeszi, Erdő utca 101.
Tel.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB ID number: 2409

Manufacturer's Declaration

In relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	KEROX Ltd.
Manufacturer address and contact details	H-2038 Sóskút, 1. Kerox street CEO: József VERÉB; +36 20 772 9197 PRRC: Sándor VULKÁN; +36 30 827 5083 namesurname@kerox.net
Single Registration Number (SRN) (if available)	HU-MF-000031741

Authorised Representative name (if applicable)	N/A
Authorised Representative address and contact details.	N/A
Single Registration Number (SRN) (if available)	N/A

Notified body name (if applicable)	CE Certiso Kft. ☒See attached schedule
Notified body number (if applicable)	2409 ☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	144870-19-03-30 ☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	29 March 2024. ☒ See attached schedule
End date of extended validity/transition period	31 December 2028. See attached K-2023/113 / 19-09-2023 issued by NB2409, CE Certiso

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

*FORM SOURCE: MedTech Europe: https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2023-607/

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule.

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  ☒ Expired**/**expires after 20 March 2023:

  Choose one applicable statement:

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

*FORM SOURCE: MedTech Europe: https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2023-607/

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☒ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: KEROX Ipari és Kereskedelmi Kft.

Location & Date: 26 September 2023.

Signature, Print Name, Title: Sándor VULKÁN, KEROX' QS director & PRRC

Contact Details (at least email): sandorvulkan@kerox.net
M: +36 30 827 5083;
Phone: +36 23 560 700 / ext. 133

*FORM SOURCE: MedTech Europe: https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2023-607/

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
KEROX ZIRCOSTAR High Strength (HS) Cirkónium dioxid tömb 5996612CSD0000UD 5996612CSS0000ZJ	144870-19-03-30	29 March 2024.	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	31 December 2028.	N/A
KEROX ZIRCOSTAR High Translucent (HT) Cirkónium dioxid tömb 5996612CTD0000US 5996612CTS000022	144870-19-03-30	29 March 2024.	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	31 December 2028.	N/A
KEROX ZIRCOSTAR Ultra High Translucent (UHT) Cirkónium dioxid tömb 5996612CUD0000V7 5996612CUS00002F	144870-19-03-30	29 March 2024.	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	31 December 2028.	N/A
KEROX ZIRCOSTAR High Translucent Multilayer (HTML)	144870-19-03-30	29 March 2024.	CE Certiso Orvos- és Kórháztechnikai	CE Certiso Orvos- és Kórháztechnikai	31 December 2028.	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

*FORM SOURCE: MedTech Europe: https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2023-607/

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Cirkónium dioxid tömb 5996612C1A0000DX 5996612C1D0000EY			Ellenőrző és Tanúsító Kft.; NB number 2409	Ellenőrző és Tanúsító Kft.; NB number 2409		
KEROX ZIRCOSTAR Ultra High Translucent Multilayer (UTML) Cirkónium dioxid tömb 5996612C2A0000EC 5996612C2D0000FD	144870-19-03-30	29 March 2024.	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	31 December 2028.	N/A
KEROX ZIRCOSTAR 3DML Szín- és transzlucencia-átmenetes ("háromdimenziós") cirkónium dioxid tömb 5996612C3S0000LX	144870-19-03-30	29 March 2024.	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.; NB number 2409	31 December 2028.	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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