Kaz Europe Sàrl
Q-Center, Route de la Chaux 4
CH-1030 Bussigny
Switzerland

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under 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	**Kaz Europe Sàrl**
Manufacturer address and contact details	**Q-center, Route de la Chaux 4 1030 Bussigny, Switzerland**
EU Single Registration Number (SRN)	**CH-MF-000029980**
Swiss Single Registration Number (Swiss SRN)	**CHRN-MF-20000627**

European Authorised Representative name	**Obelis, S.A.**
European Authorised Representative address	**Bd. Général Wahis, 53 1030 Brussels, Belgium**
Single Registration Number (SRN)	**BE-AR-000000106**

Notified body name	**DQS Medizinprodukte GmbH** See attached schedule for more details
Notified body number	**0297** See attached schedule for more details
Directive Certificate number(s) to which this confirmation is made	**93/42/EEC** See attached schedule for more details
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	**May 26, 2024** See attached schedule for more details
End date of extended validity/transition period	**Dec 31, 2028** See attached schedule for more details

[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.

Kaz Europe Sàrl
Q-Center, Route de la Chaux 4
CH-1030 Bussigny
Switzerland

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** 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** as listed above or in the attached schedule

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Certificate covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.

☑ 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.

☐ 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:** Not applicable

➢ **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 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.

[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

Kaz Europe Sàrl
Q-Center, Route de la Chaux 4
CH-1030 Bussigny
Switzerland

Signed for and on behalf of the manufacturer:

KAZ Europe Sàrl

Michael Burke
General Manager EMEA

Signature

Maud Giorgi
QMS & RA Manager, EMEA
Contact details:
Quality_EMEA@helenoftroy.com
Signature

Date	May 06, 2024
Place	Bussigny, Switzerland

Kaz Europe Sàrl
Q-Center, Route de la Chaux 4
CH-1030 Bussigny
Switzerland

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 to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
BST200	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BNT300	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BNT400	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT3030	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT6030	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT6515	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT6520	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
IRT6525	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
PRT1000	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
PRT2000	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
LF40, LF20	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BUA5000	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BUA6150	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BUA6350	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A
BNA100	381008 MR5	May 26, 2024	DQS Medizinprodukte GmbH, 0297	DQS Medizinprodukte GmbH, 0297	Dec 31, 2028	N/A

[3] for devices with MDD certificate the identification should be as in the certificate