EC Declaration of Conformity

We, **Kaz Europe Sàrl**, Place Chauderon 18, 1003 Lausanne, Switzerland declares under our sole responsibility that the product to which this declaration relates is in conformity with the following standard(s) or other normative document(s) and proves the conformity of the designated product with the provisions of the below Directive(s):

- **MDD - Council Directive 93/42/EEC of 14 June 1993 concerning medical devices**
- **RoHS - Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment**

Name

Braun ThermoScan 7 /ThermoScan 5 / Thermoscan 6 / Thermoscan 7+ - Infrared Ear Thermometers
IRT6520, IRT6030, IRT6020, IRT6515 and IRT6525 series

Type or model

IRT6520
IRT6520MNLA
IRT6520WE
IRT6520BWE
IRT6520NOEE
IRT6520LA
IRT6525
IRT6525NOEE
IRT6525MNLA
IRT6525WE
IRT6525KO
IRT6525AP
IRT6525AU
IRT6020NOEE
IRT6020MNLA
IRT6030
IRT6515NOEE
IRT6515MNLA

IRT6520WEGP (IRT6520WE + a Toy thermometer)
IRT6520NOEEGP (IRT6520EEE + a Toy thermometer)
IRT6520MNLAGP (IRT6520MNLA + a Toy thermometer)
IRT6525MNLAGP (IRT6525MNLA + a Toy feel and learn book)
IRT6525WEGP (IRT6525WE + a Toy feel and learn book)
XXX (this is a fantome code, there is no packaging)

Note: IRT6520WEGP, IRT6520NOEEGP, IRT6520MNLAGP, IRT6525WEGP, IRT6525MNLAGP are sold with a Toy into the packaging. The toy is covered by his own EC Declaration of Conformity under the Toy Safety Directive with Lechner Ges.m.b.H, Osterreich as manufacturer.

Standards Applied:

Standard Reference	Edition	Title
EN ISO 13485	2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN 60601-1	2006 +A1:2013	Medical electrical equipment - Part 1: General requirements for safety and essential performance.
EN 60601-1-2	2015	Medical electrical equipment – part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests.
EN 60601-1-6	2010/A1:2013	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability.
EN 60601-1-11	2015	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN ISO 14971	2019	Medical devices — Application of risk management to medical devices.
EN 62304	2006 A1:2008	Medical device software - Software life-cycle processes
EN ISO 10993-1	2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing.
EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

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ISO 10993-10	2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
EN 62366-1	2015	Medical devices — Application of usability engineering to medical devices.
EN ISO 80601-2-56	2017	Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical
EN 12470-5	2000+A1:2009	Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers
EN 1041	2008/A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1	2016	Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1 – General requirements
ASTM E1965-98	2016	Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
EN ISO 14155	2011/AC:2011	Clinical investigation of medical devices for human subjects - Good clinical practice

The Technical Documentation is the responsibility of: Kaz Europe Sàrl, Place Chauderon 18, CH-1003 Lausanne, Switzerland

Additional information:

For Medical Device Directive 93/42/EC	
Regulatory class (MDD, Annex IX):	class IIa (Annex IX rule 10)
Conformity assessment procedure:	Annex V
GMDN	17887
UMDNS	17-887
Notified Body	DQS Medizinprodukte GmbH August Schanz Str. 21 D-60433 Frankfurt, Germany Registration number: 0297
EC Certificate	-381008 MR5 -See Annex: Manufacturer's Declaration signed on 06 May 2024
EN ISO 13485 Certificate	381008 MP2016

Authorized Representative in Europe: Obelis, S.A.
Address: Bd. Général Wahis, 53
1030 Brussels, Belgium

Authorized Representative in Turkey: Sistem Çözüm Ortaklığı Satış Dağıtım Tic. Ltd. Şti.
Address: Ortaklar Cad. Bahçeler Sok.
18 İş Merkezi K:3 D:5 Mecidiyeköy
34394 İstanbul, Turkey
Tel: +90 212 216 2950

This declaration of conformity is valid until December 31, 2028.

Michael Burke		Maud Giorgi	
General Manager EMEA	Legally binding signature	PRRC, QMS & Regulatory Affairs Manager EMEA	Legally binding signature

Bussigny	May 13, 2024	Company Stamp:
Place	Date	

Helen of Troy
Kaz Europe Sàrl
Route de la Chaux 4
1030 Bussigny sur Lausanne
Switzerland
Tel. +41 21 644 01 10

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

Helen of Troy

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