# DECLARATION OF CONFORMITY TO COUNCIL REGULATION EU 2017/745 CONCERNING MEDICAL DEVICES

Manufacturer: Qingdao Hisense Medical Co., Ltd.
No. 399 Songling Road, Laoshan District 266100, Qingdao, Shandong, P. R. China
SRN: CN-MF-000047224

| | |
|---|---|
| Medical Device: | Ultrasound Diagnostic System<br>Model: See appendix.<br>GENERAL PURPOSE ULTRASOUND SCANNERS<br>GMDN 40761, CND Z11040101 |
| Classification - Annex VIII: | Class IIa, rule 10 |
| Conformity assessment Route: | Annex IX |
| Basic UDI-DI code (GMN): | 697831195Ultrasound9F |
| Identification and traceability: | Model and Series Number |

We, Qingdao Hisense Medical Co., Ltd, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council REGULATION EU 2017/745 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer and European Representative.

| | |
|---|---|
| Notified Body: | DEKRA Certification B.V.<br>Meander 1051, 6825 MJ Arnhem<br>P.O. Box 5185, 6802 ED Arnhem,The Netherlands |
| Identification number | CE 0344 |
| (EC) Certificate(s): | 6097607CE01 |
| EU REP<br>European Representative: | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestrasse 80, 20537 Hamburg, Germany<br>SRN: DE-AR-000000001 |

Start of CE-marking: Dec-20-2021

Place, Date of Declaration: Qingdao P.R.C., Apr-14-2025

Signature: Guangbin Wang

Name: Guangbin Wang

Position: Person responsible for regulatory compliance

We, as the manufacturer, declare under our sole responsibility for the declaration of conformity.

Digitally signed by Iurchevici Valeriu
Date: 2026.04.24 13:22:22 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

# DECLARATION OF CONFORMITY TO COUNCIL REGULATION EU 2017/745 CONCERNING MEDICAL DEVICES

## Appendix: device list

| Description | Model |
|---|---|
| Ultrasound Diagnostic system | HD60、HD60S、HD60G、HD60Q、HD60T、HD60E、HD60EXP、HD60Pro;<br>HD58EXP、HD58Pro、HD58Plus、HD58;<br>HD59EXP、HD59Pro、HD59Plus、HD59;<br>HD62EXP、HD62Pro、HD62Plus、HD62;<br>HD55、HD55S、HD55G、HD55Q、HD55T、HD55E、HD55Plus;<br>HD50、HD50S、HD50G、HD50Q、HD50T、HD50E、HD50Plus;<br>HD48、HD48S、HD48G、HD48Q、HD48T、HD48E、HD48Plus;<br>HD45、HD45S、HD45G、HD45Q、HD45T、HD45E、HD45Plus;<br>HD42、HD42S、HD42G、HD42Q、HD42T、HD42E、HD42Plus;<br>HD40、HD40S、HD40G、HD40Q、HD40T、HD40E、HD40Plus;<br>HD35、HD35S、HD35G、 HD35Q、HD35T、HD35E、HD35Plus;<br>HD30、HD30S、HD30G、HD30Q、HD30T、HD30E、HD30EXP、HD30Pro;<br>HD25、HD25S、HD25G、HD25Q、HD25T、HD25E、HD25EXP、HD25Pro;<br>HD20、HD20S、HD20G、HD20Q、HD20T、HD20E、HD20EXP、HD20Pro; |
| Accessories: Probe | L15-5E, L12-3EB, L15-5EB, L15-5E, L9-3E, L14-6E, L9-3A, L12-4L, L12-3E,<br>SC7-1E, SC8-2E,<br>C5-2A, C5-2L, C5-1E,<br>P5-1A, P8-2EJ, P4-1EL, P4-1EB, P4-1L, P4-1E,<br>DC6-2A, DC7-2A, DE10-3E, MC11-3A,<br>E9-3E, E9-4E, E9-4EL, E9-4L, E9-4B, ECL11-4E |

# CERTIFICATE

Number: 6221932

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## Qingdao Hisense Medical Co., Ltd.

**No. 399 Songling Road, Laoshan District**
**266100, Qingdao, Shandong,**
**P. R. China**

including the implementation meets the requirements of the standard:

# ISO 13485:2016
# EN ISO 13485:2016

Scope:
Design, manufacture, distribution and servicing of Ultrasound Diagnostic Systems

Certificate expiry date: 1 July 2028
Certificate effective date: 1 July 2025
Certified since: 1 July 2025

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Certification Manager



MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396

# ADDENDUM

To certificate: 6221932

The management system of the organization(s) and/or location(s) of:

## Qingdao Hisense Medical Co., Ltd.

**No. 399 Songling Road, Laoshan District**
**266100, Qingdao, Shandong,**
**P. R. China**

| Certified organization(s) and/or locations: | Different scope |
|---|---|
| **No. 218 Qianwangang Road, Economy & Technology Development Zone 266555, Qingdao, Shandong, P. R. China** | Manufacture of Ultrasound Diagnostic Systems |

Addendum expiry date: 1 July 2028
Addendum effective date: 1 July 2025

**Number: 6097607CE01**

# EU Quality Management System Certificate

**Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III**

Manufacturer:

## Qingdao Hisense Medical Co., Ltd.

**No. 399 Songling Road, Laoshan District**
**266100, Qingdao, Shandong**
**P. R. China**
**SRN ID.: CN-MF-000047224**

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

# 0344

**Supplement to certificate: 6097607CN**

**Authorized Representative:**
**Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg
Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **20 December 2021** Date: **8 September 2025** Expiry date: **1 December 2026**



DEKRA Certification B.V. is Notified Body with ID no 0344

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**Number: 6097607CE01**

# EU Quality Management System Certificate

**Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III**

This certificate covers the following device(s) / groups of device(s):

| **Active non-implantable imaging devices utilising non-ionizing radiation (MDA0202, class IIa)** |
|---|
| **Device Name:** Ultrasound diagnostic systems HD 20 series to HD 60 series |
| **Device Name:** Ultrasound diagnostic systems HD 80 series |
| **Device Name:** Ultrasound diagnostic systems H7 and Aisense series |

Conditions for or limitations to the validity of this certificate:

- N/A

**Certificate History**

*Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.*

| Revision | Date of Issue certificate | Certification Notice Reference | Action |
|---|---|---|---|
| 0 | 20-12-2021 | 6097607CN01 | First issue |
| 1 | 1-1-2024 | 6097607CN02 | Revised |
| 2 | 14-4-2025 | 6097607CN04 | Revised |
| 3 | 8-9-2025 | 6097607CN06 | Revised |

First Issued: **20 December 2021** Date: **8 September 2025** Expiry date**: 1 December 2026**



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