

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

Appendix: device list

Description	Model
Ultrasound Diagnostic system	HD80、HD80Pro、HD80EXP、HD80Plus、HD80M、HD80S、 HD80G、HD80Q、HD80T、HD80E , HD82、HD82Pro、HD82EXP、HD82Plus、HD82M、HD82S、 HD82G、HD82Q、HD82T、HD82E, HD85、HD85Pro、HD85EXP、HD85Plus、HD85M、HD85S、 HD85G、HD85Q、HD85T、HD85E, HD86、HD86Pro、HD86EXP、HD86Plus、HD86M、HD86S、 HD86G、HD86Q、HD86T、HD86E, HD88、HD88Pro、HD88EXP、HD88Plus、HD88M、HD88S、 HD88G、HD88Q、HD88T、HD88E, HD90、HD90Pro、HD90EXP、HD90Plus, HD70、HD70Pro、HD70EXP、HD70Plus、HD70M、HD70S、 HD70G、HD70Q、HD70T、HD70E, HD72、HD72Pro、HD72EXP、HD72Plus、HD72M、HD72S、 HD72G、HD72Q、HD72T、HD72E, HD75、HD75Pro、HD75EXP、HD75Plus、HD75M、HD75S、 HD75G、HD75Q、HD75T、HD75E, HD78、HD78Pro、HD78EXP、HD78Plus、HD78M、HD78S、 HD78G、HD78Q、HD78T、HD78E
Accessories: Probe	L12-3E\L15-5E\L9-3E\L15-5E\L21-9E\L14-6E\L12-3EB\L15- 5EB\SC7-1E\C5-1E\SC8-2E; P8-2E\JP4-1E\L\P5-1A\XP5-1E\VP4-1EB; DC7-2A\DC7-2E\DE10-3E\MC11-3A\ECL11-4E; E9-3E\E9-4E\E9-4E.



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

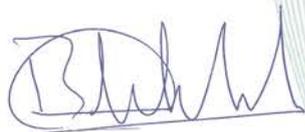
Certificate expiry date: 1 July 2028

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

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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:

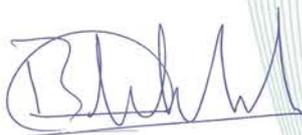
Shanghai International Holding Corp. GmbH (Europe)

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**

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

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

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

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