



National Institute of Medical Device Safety Information

#303-1, Mario Tower, 28, 30-gil, Digital-ro, Guro-gu, Seoul, Korea(08389),
Tel: +82-2-860-4450, Fax: +82-2-860-4479

Certificate of Free Sales

No. of Certificate : 20220086605
Exporting(certifying) country : Republic of Korea
Importing(requesting) country :

The National Institute of Medical Device Safety Information, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act, and the following product(s) is(are) permitted to be freely sold in domestic and overseas markets.

○ Applicant (=Product-license holder)

(This certificate shall not be issued to others than the product-license holder)

- Name : Siemens Healthineers Ltd.

- Address : 2nd~3rd Floor, 143, Sunhwan-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do

- Registered No : Manufacturer 2147

No. and date of product-license, comments	Classification
15-4225 / OCT. 29. 2015	Ultrasound imaging system, general-purpose [2]
15-453 / MAR. 31. 2015	Ultrasound system, imaging, dianostic, mobile [2]
16-4597 / JUL. 19. 2016	Ultrasound imaging system, general-purpose [2]
17-4987 / DEC. 19. 2017	Ultrasound imaging system, general-purpose [2]
19-4607 / JUL. 22. 2019	Ultrasound imaging system, general-purpose [2]

※ Attached, if necessary (approved product information)

☒ Model(Export Name) ☐ Medical Device Accessories ☐ Manufacturer/Legal manufacturer
☐ Combined/Composite medical device

o Do the facilities and operations conform to KGMP as recommended by the Ministry of Food and Drug Safety?

☒ Yes ☐ No

Issued date : JUL. 25. 2022 (Certificate No.20220086605)

Certified by

이성희

Director of Medical Device Certification Department
National Institute of Medical Device Safety Information

The National Institute of Medical Device Safety Information(NIDS) is related organization of Ministry of Food and Drug Safety and established under Article 42 of the Medical Device Act.
The Minister of Food and Drug Safety authorized the director of NIDS to issue this free sales certificate under the Article 44 (2) of the Medical device Act.



Attachment

Product License No. : 15-4225 (SEP. 01. 2021)

Classification : Ultrasound imaging system, general-purpose

Model(Export Name)

ACUSON NX3 Diagnostic Ultrasound System(P/N 11235612) and supported transducers(CH5-2(P/N 10789386), VF10-5(P/N 10789387), VF12-4(P/N 11575186), EC9-4(P/N 10789383), P4-2(P/N 10789385), C8F3(P/N 10786652), 10MC3(P/N 11284842), 11L4(P/N 11361584), BP10-3(P/N 11336164))

ACUSON NX3 Elite Diagnostic Ultrasound System(P/N 11235411) and supported transducers(P8-4(P/N 10789389), CH5-2(P/N 10789386), VF10-5(P/N 10789387), VF12-4(P/N 11575186), VF13-5sp(P/N 07471506), VF16-5(P/N 10785041), EC9-4(P/N 10789383), P4-2(P/N 10789385), CW2(P/N 10789380), CW5(P/N 10789381), C8F3(P/N 10786652), EC10-5w(P/N 10787072), C8-5(P/N 10348181), 11L4(P/N 11361584), 10MC3(P/N 11284842), V5Ms(P/N 11361462), BP10-3(P/N 11336164))

Product License No. : 15-453 (OCT. 19. 2021)

Classification : Ultrasound system, imaging, dianostic, mobile

Model(Export Name)

ACUSON P500 Ultrasound System(P/N 10785577) and supported transducers(CH5-2 (P/N 10136141), VF10-5 (P/N 10136142), VF13-5 (P/N 10789372), P4-2 (P/N 10136143), EC9-4 (P/N 10136144), VF16-5 (P/N 11014552), P8-4 (P/N 11014543), CW2 (P/N 10789380), CW5 (P/N 10789381), L10-5v (P/N 11319682), 11M3(P/N 11284923), 5VT(P/N 11370949), 18H5(P/N 11284924))

Product License No. : 16-4597 (APR. 07. 2021)

Classification : Ultrasound imaging system, general-purpose

Model(Export Name)

ACUSON NX2 Diagnostic Ultrasound System (P/N 11284381) with the supported transducers (CH5-2 (P/N 10789386), VF10-5 (P/N 10789387), EC9-4 (P/N 10789383), P4-2 (P/N 10789385), C8F3 (P/N 10786652), C5-2v (P/N 11284925), L10-5v (P/N 11284926), 10MC3 (P/N 11284842))

ACUSON NX2 Elite Diagnostic Ultrasound System (P/N 11284500) with the supported transducers (CH5-2 (P/N 10789386), VF10-5 (P/N 10789387), EC9-4 (P/N 10789383), P4-2 (P/N 10789385), C8F3 (P/N 10786652), C5-2v (P/N 11284925), L10-5v (P/N 11284926), 10MC3 (P/N 11284842), CW2 (P/N 10789380), CW5 (P/N 10789381))

Product License No. : 17-4987 (JUL. 20. 2022)

Classification : Ultrasound imaging system, general-purpose

Model(Export Name)

ACUSON Juniper Diagnostic Ultrasound System(P/N:11335791) and supported transducers (11L4(P/N:11284844),8V4(P/N:11284847),16L4(P/N:11284846),10V4(P/N:11319697), 5C1(P/N:11268278), 7C2(P/N:11268277),12L3(P/N:11575183),5P1(P/N:11014154), 10MC3(P/N:11268679),18H5(P/N:11284924), 11M3(P/N:11284923),9MC3(P/N:11284920),8VC3(P/N:11284921),9VE3(P/N:11284922),CW2(P/N:10789380), CW5(P/N:10789381),CW8(P/N:11503525),13L4(P/N:11361589),5VT(P/N:11370949),14L4(P/N:11503732), 6C1(P/N:11503481))

ACUSON Juniper Select Diagnostic Ultrasound System(P/N: 11653093) and supported transducers (5C1(P/N: 11268278), 5P1(P/N: 11014154), 8VC3(P/N: 11284921), 10MC3(P/N: 11268679), 11L4(P/N: 11284844), 12L3(P/N: 11575183), CW2(P/N: 10789380), CW5(P/N: 10789381))

Product License No. : 19-4607 (SEP. 01. 2021)

Classification : Ultrasound imaging system, general-purpose

Model(Export Name)

ACUSON Redwood Diagnostic Ultrasound System (P/N 11503314) with the supported transducers (4V1(P/N 11014576), 5V1(P/N 11291796), 8V3(P/N: 11014578), 10L4(P/N 10787114), 14L5(P/N 11254090), 18L6(P/N: 11575184), 5C1(P/N 11291794), 9C3(P/N 11575182), 9EC4(P/N 10787117), CW2(P/N 10789380), CW5(P/N 10789381), 10V4(P/N 11014579), V5Ms(P/N 11013704), 7VC2(P/N 11289565), 9VE4(P/N 11289564), 18H6(P/N 11289567))