

Certificate

Standard **ISO 13485:2016**

Certificate Registr. No. 81 105 1432155

Certificate Holder: **Medical Solutions Business Division
Medical Business Group
Sony Corporation**

4-14-1 Asahi-cho, Atsugi-shi, Kanagawa, 243-0014 Japan

including the locations according to annex

Scope: Design and development, control of contract manufacture and sales of medical printer, medical monitor, medical imaging camera, medical recorder, medical image transmission/recording system and medical head-mount image processor unit.

Proof has been furnished by means of an audit that the requirements of ISO 13485:2016 are met.

Validity: The certificate is valid from 2017-09-12 until 2020-09-11
First certification 2014

2017-09-05



TÜV Rheinland Japan Ltd.
3-19-5 Shin-Yokohama, Kohoku-ku,
Yokohama 222-0033, Japan

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Annex to certificate

Standard **ISO 13485:2016**

Certificate Registr. No. 81 105 1432155

No.	Location	Scope
81 105 1432155/01	Medical Solutions Business Division Medical Business Group Sony Corporation 4-14-1 Asahi-cho, Atsugi-shi, Kanagawa, 243-0014 Japan	Design and development, control of contract manufacture and sales of medical printer, medical monitor, medical imaging camera, medical recorder, medical image transmission/recording system and medical head-mount image processor unit.
81 105 1432155/02	Medical Solutions Business Division Medical Business Group Sony Corporation 30 Ibarajima, Ooya-cho, Inazawa-shi, Aichi, 492-8545 Japan	Design verification of medical monitor.
81 105 1432155/03	Medical Solutions Business Division Medical Business Group Sony Imaging Products & Solutions Inc. 4-14-1 Asahi-cho, Atsugi-shi, Kanagawa, 243-0014 Japan	Purchasing control (ordering and receiving) of medical printer, medical monitor, medical imaging camera, medical recorder, medical image transmission/recording system and medical head-mount image processor unit.

2017-09-05



TÜV Rheinland Japan Ltd.
3-19-5 Shin-Yokohama, Kohoku-ku,
Yokohama 222-0033, Japan

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SONY

Sony Belgium, bijkantoor van Sony Europe Limited
Da Vincilaan 7 – D1, B-1935 Zaventem
Phone: +32 (0) 2 706 43 11 - Fax : +32 (0) 2 706 43 20

EU DECLARATION OF CONFORMITY

Model Name: UPT-510BL

1999/5/EC, R&TTE
93/42/EEC, 2007/47/EC, MDD
2011/65/EU, RoHS



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Phone: +32 (0) 2 706 43 11 - Fax: +32 (0) 2 706 43 20

EU DECLARATION OF CONFORMITY

1. Model No.:

UPT-510BL

2. Name and address of the manufacturer's authorised representative:

Sony Belgium, bijkantoor van Sony Europe Limited, Da Vincilaan 7-D1, 1935 Zaventem, Belgium

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

4. Object of the declaration:

Blue Thermal Film

5. The object of the declaration described above is in conformity with:

1999/5/EC, R&TTE

6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:

Art.3.1(a): EN 60950-1:2006 + A1:2010 + A2:2013 + A11:2009 + A12:2011, EN 50364:2010

Art.3.1(b): EN 55032:2012, EN 55024:2010, EN 301489-1:2011 (V1.9.2), EN 301489-3:2013 (V1.6.1)

Art.3.2: EN 300330-2:2015 (V1.6.1), EN 302291-2:2005 (V1.1.1)

7. Where applicable, the notified body (name and number), description of intervention and certificate

-

8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:

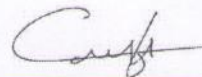
-

9. Additional information:

-

Signed for and on behalf of: **Sony Belgium, bijkantoor van Sony Europe Limited**

Zaventem, 2016-12-16



David Choudin
Director
Branch Manager



Sony Europe Limited. A company registered in England and Wales
Registered Address: The Heights, Brooklands, Weybridge, Surrey. KT13 OXW, United Kingdom. - Registered company number: 2422874

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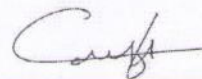
Sony Belgium, bijkantoor van Sony Europe Limited
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EU DECLARATION OF CONFORMITY

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3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
4. Object of the declaration:
Blue Thermal Film
5. The object of the declaration described above is in conformity with:
93/42/EEC, 2007/47/EC, MDD
6. Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared:
EN 60601-1-2:2007, EN 60601-1:2006
7. Additional information:
Following the provisions for Class I devices

Signed for and on behalf of: Sony Belgium, bijkantoor van Sony Europe Limited

Zaventem, 2016-12-16



David Choudin
Director
Branch Manager



Sony Europe Limited, A company registered in England and Wales
Registered Address: The Heights, Brooklands, Weybridge, Surrey. KT13 OXW, United Kingdom. - Registered company number: 2428874

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Da Vincilaan 7 – D1, B-1935 Zaventem
Phone: +32 (0) 2 706 43 11 - Fax : +32 (0) 2 706 43 20

EU DECLARATION OF CONFORMITY

Model Name: UPT-517BL

1999/5/EC, R&TTE
93/42/EEC, 2007/47/EC, MDD
2011/65/EU, RoHS



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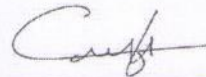
Sony Belgium, bijkantoor van Sony Europe Limited
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Phone: +32 (0) 2 706 43 11 - Fax: +32 (0) 2 706 43 20

EU DECLARATION OF CONFORMITY

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Art.3.1(b): EN 55032:2012, EN 55024:2010, EN 301489-1:2011 (V1.9.2), EN 301489-3:2013 (V1.6.1)
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8. Where applicable, description of accessories and components, including software, which allow the radio equipment to operate as intended and covered by the EU declaration of conformity:
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9. Additional information:
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Signed for and on behalf of: Sony Belgium, bijkantoor van Sony Europe Limited

Zaventem, 2016-12-16



David Choudin
Director
Branch Manager



Sony Europe Limited. A company registered in England and Wales
Registered Address: The Heights, Brooklands, Weybridge, Surrey. KT13 OXW, United Kingdom. - Registered company number: 2422876

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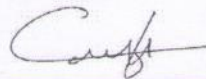
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