Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2019096-1

Organization: Sony Storage Media Manufacturing Corporation
Tagajo Site
3-4-1 Sakuragi, Tagajo-shi
Miyagi
985-0842 Japan

Scope: Manufacture of print media (dye-sublimation color printing pack) for medical use
Production control of print media (thermal film, thermal print media, dye-sublimation color printing pack) for medical use

Digitally signed by Captari Vladimir
Date: 2023.02.05 11:06:26 EET
Reason: MoldSign Signature
Location: Moldova

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Report No.: 150226433-320
Effective date: 2020-10-24
Expiry date: 2023-10-23
Issue date: 2021-04-19

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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

EU DECLARATION OF CONFORMITY

(BG) ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ С ИЗИСКВАНИЯТА НА ЕС

(CS) EU PROHLÁŠENÍ O SHODĚ

(DA) EU-OVERENSSTEMMELSESERKLÆRING

(DE) EU-KONFORMITÄTSERKLÄRUNG

(EL) ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ

(EN) EU DECLARATION OF CONFORMITY

(ES) DECLARACIÓN DE CONFORMIDAD UE

(ET) ELI VASTAVUSDEKLARATSIOON

(FI) EU-VAATIMUSTENMUKAISUUSVAKUUTUS

(FR) DÉCLARATION UE DE CONFORMITÉ

(HR) EU IZJAVA O SUKLADNOSTI

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(IT) DICHIARAZIONE UE DI CONFORMITÀ

(LT) ES ATITIKTIES DEKLARACIJA

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(MT) DIKJARAZZJONI TAL-KONFORMITÀ TAL-UE

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(RO) DECLARAȚIE DE CONFORMITATE UE

(SK) VYHLÁSENIE O ZHODE EÚ

(SL) IZJAVA EU O SKLADNOSTI

(SV) EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

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

SONY

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

EU DECLARATION OF CONFORMITY (EN)

1. Model No.: UPT-510BL

2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 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:
   2017/745 (Medical Device Regulation)
   2014/53/EU (Radio Equipment)
   2011/65/EU (RoHS)

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

Medical:	EN 60601-1:2006 + A1:2013, EN 60601-1-2:2015
Radio Equipment:	EN 50364:2018, EN 62368-1:2014 + A11:2017, EN 301 489-3:2019 (V2.1.1), EN 300 330:2017 (V2.1.1)
RoHS:	EN 50581:2012

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:

Software:	-
Accessory(ies):	-
Component:	-

9. Additional information:

Classification:	Class I, MDR Annex VIII
Basic UDI-DI:	4901780PrintMediaWR
Manufacturer SRN:	[will be available after open the Eudamed]
Authorised Representative SRN:	[will be available after open the Eudamed]
Intended Purpose:	Print media for Sony's medical printer
Accessory(ies):	-
Note(s):	-

Signed for and on behalf of: Sony Corporation

Tokyo, 2020-09-07

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Reference Number: 2020EU00790

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

SONY

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

DECLARAȚIE DE CONFORMITATE UE (RO)

1. Număr model: UPT-510BL

2. Denumirea și adresa reprezentantului autorizat al producatorului: Sony Belgium, bijkantoor van Sony Europe B.V., Da Vincilaan 7-D1, 1930 Zaventem, Belgium

3. Aceasta declarație de conformitate este eliberata pe propria raspundere a producatorului: Sony Corporation, 1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan

4. Obiectul declarației: Blue Thermal Film

5. Obiectul declarației descrise mai sus este conform cu:
   2017/745 (Medical Device Regulation)
   2014/53/EU (Radio Equipment)
   2011/65/EU (RoHS)

6. Unde este valabil, se face referința la standardele armonizate relevante care au fost folosite sau la specificațiile tehnice relativ la care este declarata conformitatea:

Medical:	EN 60601-1:2006 + A1:2013, EN 60601-1-2:2015
Radio Equipment:	EN 50364:2018, EN 62368-1:2014 + A11:2017, EN 301 489-3:2019 (V2.1.1), EN 300 330:2017 (V2.1.1)
RoHS:	EN 50581:2012

7. Unde este valabil, numele și numarul organismului notificat, descrierea intervenției și certificatul:

8. Unde este valabil, descrierea accesoriilor și a componentelor, inclusiv software, care permit echipamentului radio sa funcționeze așa cum a fost destinat și acoperit de către declarația de conformitate EU:

Software:	-
Accesorii:	-
Componentă:	-

9. Informații suplimentare:

Clasificare:	Class I, MDR Annex VIII
UDI-DI de bază:	4901780PrintMediaWR
SRN Producător:	[will be available after open the Eudamed]
SRN Reprezentant Autorizat:	[will be available after open the Eudamed]
Scopul propus:	Print media for Sony's medical printer
Accesorii:	-
Notă:	-

Semnat pentru și din partea: Sony Corporation

Tokyo, 2020-09-07

Ryogo Katayama
Quality Officer
Quality Officer Group
Quality & Environmental Dept.

Numar referința: 2020EU00790

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