

EU Declaration of Conformity

Medical Devices Regulation MDR 2017/745

Concerning medical device

Company name: MusiCure in Healthcare ApS
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CVR- DK: 20292296
VAT P-number: 1004339536
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MusiCure[®]
IN HEALTHCARE

MusiCure[®]
P I L L O W

Declare that the DoC is issued under our sole responsibility of the manufacturer and belongs to the following product: MusiCure Pillow[®] GFO 20178

Object of the declaration

According to the MDR annex VIII classification rules are MusiCure Pillow[®] produced as a non-invasive device,
Classified as a class 1 medical device.

Registered by the Danish Medicine Agency with the Single registration: **Manufacturer SRN: DK-MF-000023732**

Basic UDI-DI (GMN) - 5703152MP20178AE

GTIN-13 MusiCure Pillow: DK: 5703152000007 - UK: 5703152000014 - D: 5703152000021

GTIN-14 MusiCure Pillow: DK: 05703152000007 - UK: 05703152000014 - D: 05703152000021

EUDAMED Actor registration user-ID: APP000036761



ADDITIONAL INFORMATION

1. QMS & PMS: *Appendix*
2. PI – Production Identifier - General description of the MusiCure Pillow: *Appendix*
3. GSPR – General Safety and Performance Requirements: *Appendix*
4. CER - Clinical Evaluation Report: *Appendix*
5. Ex: Published study with MusiCure Pillow from North Zealand Hospital, Denmark: *Appendix*

MusiCure Pillow Manufacturer's product no: GFO 20178

Place: DK-2830 Virum, Denmark - Date: 2022-05-10

Inge Mulvad Eje,

CEO, MusiCure in Healthcare ApS

Signed for and on behalf of MusiCure in Healthcare ApS

CE 2017/745

MU006

MusiCure®
P I L L O W

REF GFO 20178

UDI



(01) 5 7031520 00007 0




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 04-11-2022

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