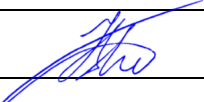


TeltoHeart labeling template

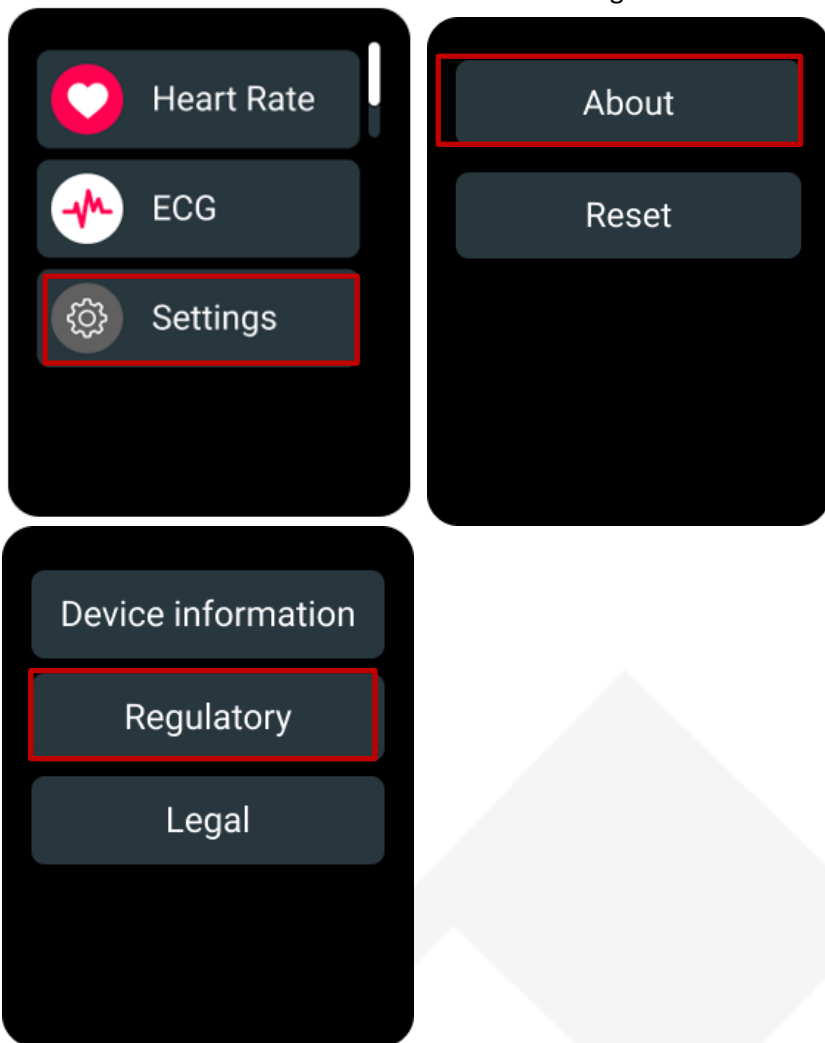
Project or product name	TeltoHeart		
Project or product ID	ECG200		
Report ID	TeltoHeart_labeling_template		
Approval			
Role	Name	Date	Signature
Author	Simonas Samavičius	2023-06-20	
Review	Gabrielė Taparauskaitė	2023-06-20	
Approval	Karolis Steckas	2023-06-20	

Document history			
Version	Date	Author	Change
1.0	2023-06-20	Simonas Samavičius	Initial document created.

1st Stage (After CE certification is obtained)

Placing of elements in TeltoHeart watch SW

TeltoHeart watch SW navigation to the labelling:

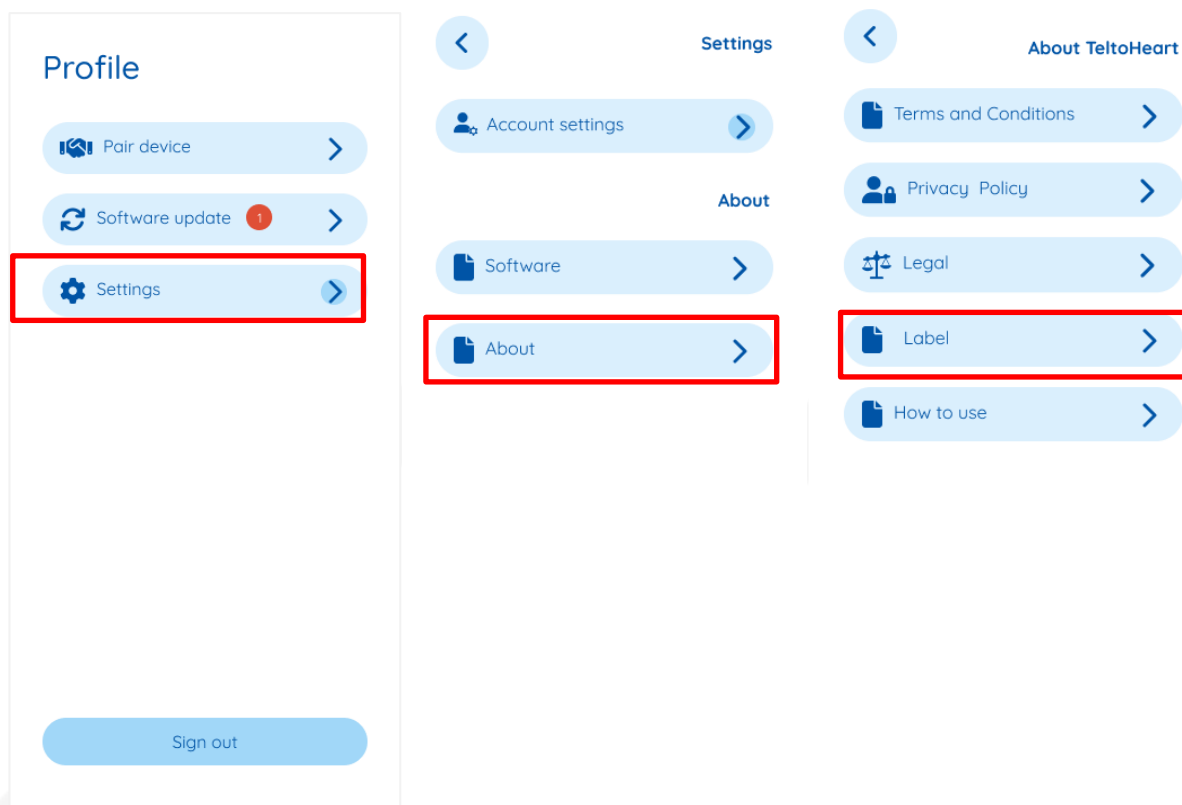


Regulatory information:



Placing of elements in MyHealth

MyHealth navigation to the labelling:



Label information:


Label

Manufacturer

TELTONIKA TELEMEDIC UAB
Naugarduko st. 102,
LT-03160,
Vilnius, Lithuania
teltonika-telemedic.com



PRODUCT NAME: **TeltoHeart**

TELTOHEART FIRMWARE VERSION: **1.0.0**

TELTOHEART FIRMWARE RELEASE DATE: **2023-03-27**

PRODUCT NAME: **MyHealth**

MYHEALTH SOFTWARE VERSION: **1.0.0**

MYHEALTH SOFTWARE RELEASE DATE: **2023-03-27**

Placing of elements in TeltoCare

TeltoCare information:

 Dashboard

Settings

- Account
Personal information
- Security
Security settings
- About >
- Terms & Conditions
- Label & Regulatory

 Settings

VILNIAUS UNIVERSITETO LIGONINĖ
SANATAROS KLINIKOS

Name Surname
namesurname@mail.com

Log Out

Label & Regulatory
Label & Regulatory information

Manufacturer

TELTONIKA TELEMEDIC UAB
Naugarduko st. 102,
LT-03160,
Vilnius, Lithuania
teltonika-telemedic.com



Product Name: TeltoHeart

TeltoHeart firmware version: 1.0.0

TeltoHeart firmware release date: 2023-01

Product Name: TeltoCare

TeltoCare software version: 1.0.0

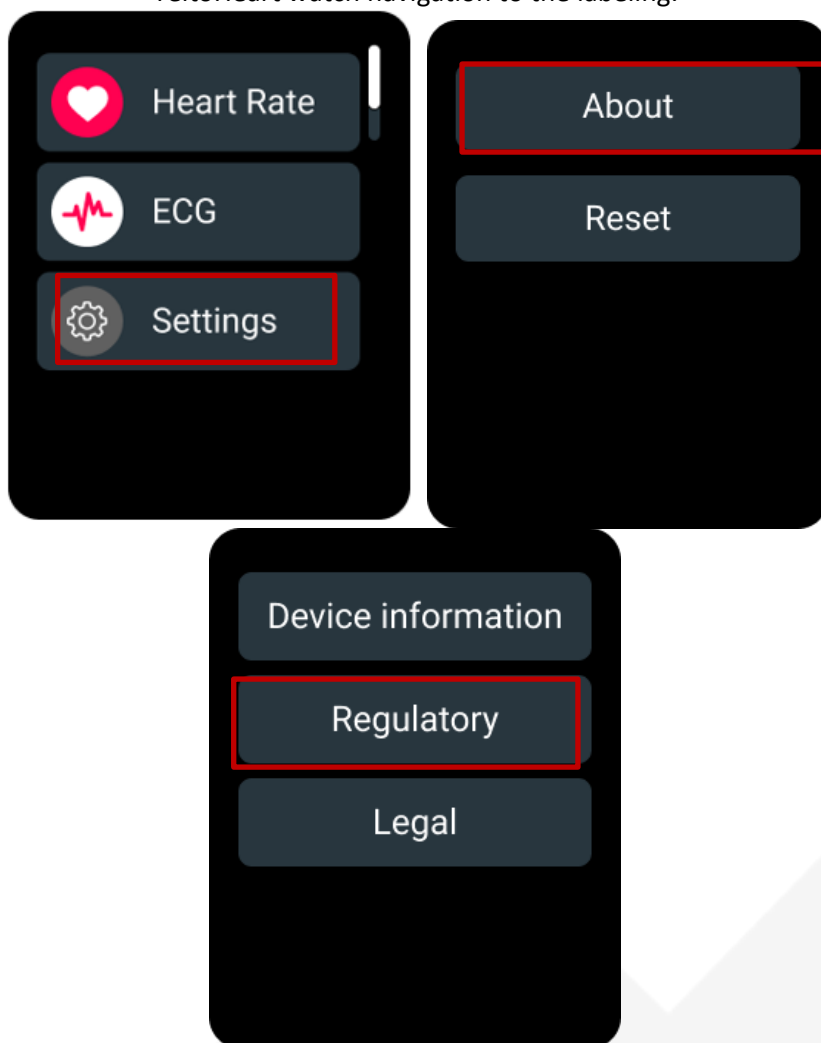
TeltoCare software release date: 2023-03-27



2nd stage (After MDR certification is obtained)

Placing of elements in TeltoHeart watch

TeltoHeart watch navigation to the labeling:



Regulatory information:

Regulatory info

Manufacturer:
TELTONIKA TELEMEDIC UAB
Naugarduko st. 102,
LT-03160, Vilnius, Lithuania
teltonika-telemedic.com

Hardware information

Europe

United Kingdom

Canada

IC ID: 27304-ECG200

U.S.

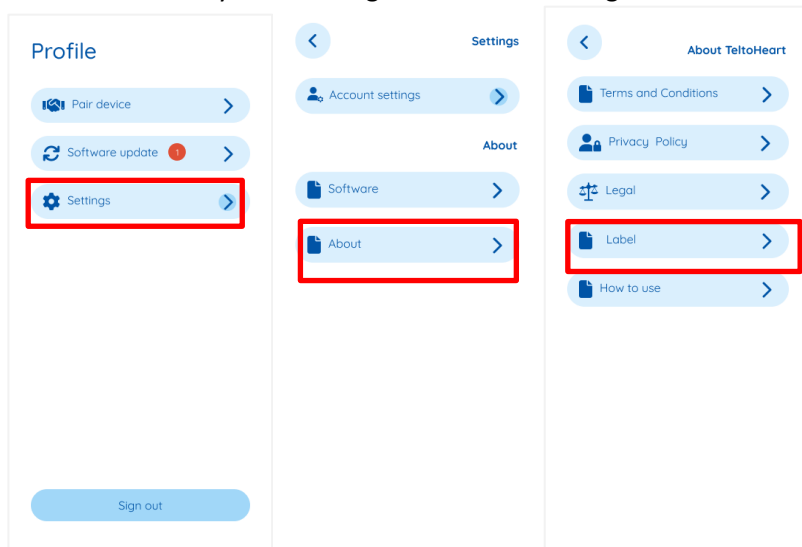
FCC ID: 2BAIF-ECG200

Software information

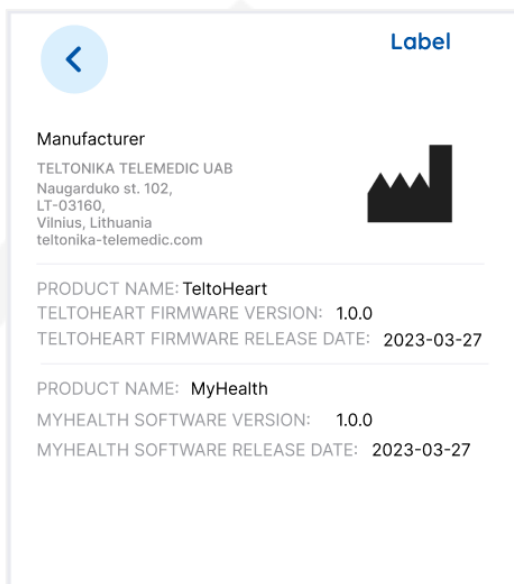
Unique Device Identification
TeltoHeart:
(01) 04779051850150
(8012) 1.0.0

Placing of elements in MyHealth

MyHealth navigation to the labeling:



Label information:



Placing of elements in TeltoCare

TeltoCare information:

Dashboard

Settings

VILNIAUS UNIVERSITETO LIGONINĖ
SANATAROS KLINIKOS

Name Surname
namesurname@mail.com

Log Out

Settings

Account
Personal information

Security
Security settings

About

Terms & Conditions

Label & Regulatory

Label & Regulatory

Label & Regulatory information

Manufacturer

TELTONIKA TELEMEDIC UAB
Naugarduko st. 102,
LT-03160,
Vilnius, Lithuania
teltonika-telemedic.com

Product Name: TeltoHeart

TeltoHeart firmware version: 1.0.0
TeltoHeart firmware release date: 2023-01

UDI (TeltoHeart): (01)04779051850150(8012)FW1.0.0

UDI

Product Name: TeltoCare

TeltoCare software version: 1.0.0
TeltoCare software release date: 2023-01

UDI (TeltoCare): (01)04779051850143(8012)SW1.0.0

UDI

CE1304

MD

TELTONIKA TELEMEDIC UAB
Naugarduko st. 102, LT-03160
Vilnius, Lithuania

Registration code 305534534
VAT number LT100013091815

Swedbank AB
LT85 7300 0101 6212 7624
S.W.I.F.T. HABALT22

Data on the company is collected and stored in the Register of Legal Entities of the Republic of Lithuania.

MANAGEMENT SYSTEM CERTIFICATION
DNV·GL
ISO 9001

MANAGEMENT SYSTEM CERTIFICATION
DNV·GL
ISO 14001

MANAGEMENT SYSTEM CERTIFICATION
DNV·GL
ISO 45001