Cortrium

C3+ | Holter Monitor

# Instructions for Use

and Technical Documentation

# 1. Introduction

This is the manual for the C3+ Holter Monitor (referred to as the "C3+" from here on). The C3+ is an ambulatory ECG recorder, which can record three channels of ECG for up to 7 days continuously. The C3+ is attached directly to a patient's torso using three third-party ECG electrodes. This manual contains all the information required to safely use the C3+.

### 1.1 Intended use

The C3+ is an ambulatory ECG recorder, intended for recording three-channel ECG for up to 7 days. The C3+ is intended for use in both healthcare and home environments. During use, the C3+ continuously records and stores ECG signals and motion data directly in the internal memory. Additionally, the C3+ has a built in Bluetooth module for streaming live data to a mobile app in order for the healthcare personnel to visually verify signal quality of the ECG (Manual for Mobile app can be found on www.cortrium.com).

Data recorded by the device can be analysed by other processing software to provide reports. This software can be either third party or designed, maintained and/or owned by Cortrium. The C3+ hardware has no capacity for automatic ECG analysis and consequently no capacity for automatically generating alerts to potentially critical cardiac conditions.

### 1.2 Patient target group

Cortrium C3+ is intended for adult and paediatric patients (above 10kg) who require ECG monitoring. The C3+ can be used on patients wearing an implanted pacemaker, but the C3+ does not detect pacemaker pulses (see Warnings section).
Final interpretation and diagnosis are the responsibility of a trained physician.

### 1.3 Intended users

The C3+ is not a consumer product. It is intended solely to be used by qualified healthcare personnel and thoroughly instructed patients.

### 1.4 Additional software

The C3+ is intended to be used with the software tools found at www.cortrium.com
These software tools are required to prepare the C3+ for use on patients and for extracting recordings after use. Instructions for the software can also be found at www.cortrium.com
Further, the C3+ is compatible with other approved CE marked 3rd party software. And it is possible to export data as EDF using Cortriums' software tools.

### 1.5 Additional hardware

The C3+ is intended to be used with 3rd party electrodes. These must be CE marked ECG electrodes with a 4 mm snap connector, adhereing to IEC 60601-1 and ISO 10993

## 2. Safety information

The following is important information on how to use the C3+ properly and safely. Carefully read this section before operating the C3+.

### 2.1 Notes on proper C3+ use

- The C3+ and Cortriums' software contain no capacity for analysing the contents of ECG recordings or providing diagnoses.
- The C3+ light patterns only reflect battery status and operation mode. The lights do not reflect cardiac health in any way and should never be interpreted as an indication of patient health.
- The C3+ is built to be operable by a healthcare professional. The patient should always be walked through all required instructions before wearing the device.

- The data recorded by the C3+ can only be used to diagnose heart-related diseases such as atrial fibrillation and arrhythmias when reviewed by a properly trained healthcare professional (e.g. a cardiologist).

### 2.2 Warnings

- Do not use C3+ before reading this manual and manual for ECG electrodes.
- Do not use C3+ without cleaning it according to instructions between patient uses.
- Do not use C3+ without preparing device as described in this document between patient uses.
- Do not allow patients to interact with the C3+, unless when directly instructed by a healthcare professional.
- Do not wear the C3+ in the shower.
- Do not touch the electrode connections while the USB cover is removed.
- Do not give the C3+ to a user or patient, without the USB cover being properly closed.
- Do not touch patient and C3+ simultaneously while C3+ is charging.
- Do not use the C3+ during MRI scans.
- Do not use the C3+ with a defibrillator.
- The C3+ cannot detect pacemaker pulses.
- Do not expose the device to strong sources of static electricity or electromagnetic fields.
- Do not leave C3+ on top of or next to other electrical equipment.
- Do not use C3+ with cables different than the one provided by Cortrium.
- Do not submerge the C3+ in liquid.
- Do not clean the C3+ with agents other than those listed in the cleaning instructions in this manual.
- Do not damage the C3+ through drops, violent shaking or crushing.
- Do not use the C3+ on patients with highly sensitive skin or known skin-related allergies.
- Do not use the C3+ on breached skin.
- Do not use the C3+ on patients below 10 kilos of body weight.
- The C3+ is not a toy. Usage on children should be under strict supervision of adults.
- Do not put C3+ into mouth under any circumstances.
- Do not alter the C3+. Any modification of the C3+ is strictly prohibited.

### 2.3 Contra indications and undesirable side effects

- The C3+ device should not be used for patients that have, life-threatening conditions that could result in immediate danger.
- The C3+ should not be used on breached skin.
- ECG electrodes may cause a patient's skin to react with irritation or reddening. Consult information provided with the electrodes for more information.
- As an end user, in case of side effects please consult your physician.

# 3. Device description

The following section describes the features of the C3+, accessories and accompanying information.

### 3.1 Included components

The C3+ comes with the following included in the package:

- The Cortrium C3+ Holter Monitor
- A micro-USB cable for charging and data extraction
- Short manual with reference to Instruction for Use and Technical Documentation (this document) also found on www.cortrium.com/manuals/

### 3.2 Accessories

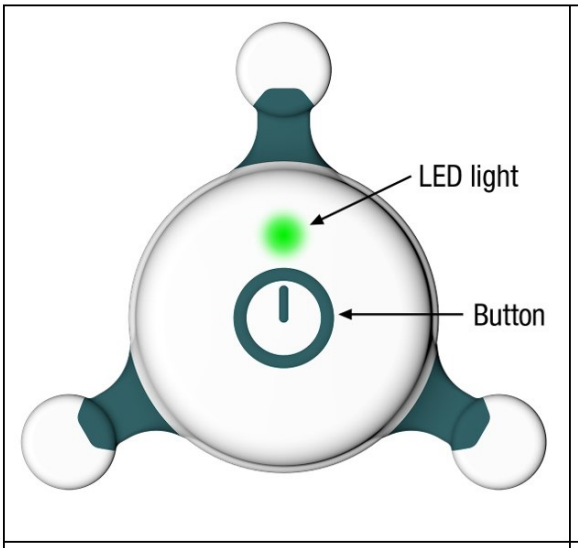
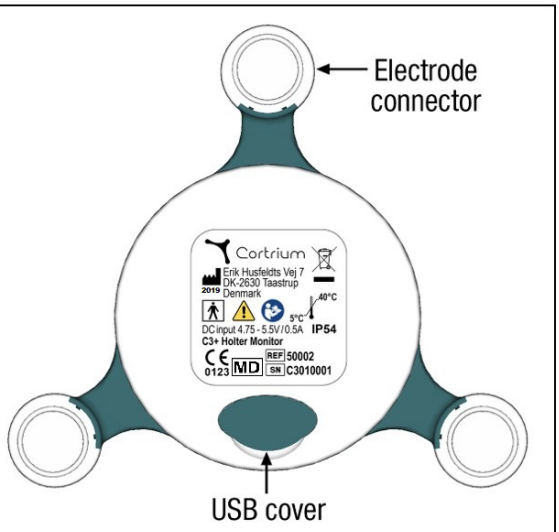
The C3+ requires the following to function as intended:

- Three third-party ECG electrodes per patient use (not supplied with device)
- The software tools found on www.cortrium.com

### 3.3 Device layout and light

The C3+ has three connectors for ECG electrodes, a single button at the center as well as an LED indicator. A USB port can be found on the back of the device.

The button is used to start recordings and to log patient events in the C3+'s internal memory as well as connect the device via Bluetooth and turn the device off.

| Front | Back |
| --- | --- |
|  |  |
| *The C3+ Holter Monitor front.*<br>*Button and light location shown.* | *USB-port cover location shown.*<br>*The device has three electrode connectors.* |
| *The C3+ Holter Monitor front.*<br>*Button and light location shown.* | *USB-port cover location shown.*<br>*The device has three electrode connectors.* |

C3+ Recordings are stored in an internal memory. Recordings can be transferred and removed from the device via the device's micro-USB port, when interfaced with the Cortrium software tools. The C3+ contains a non-replaceable, rechargeable Lithium battery.

The C3+ is recharged via the device's micro-USB-port.

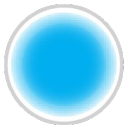
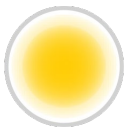
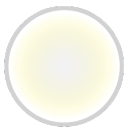
### 3.4 Interfaces

The C3+ is intended to interface with a PC using the accompanying USB-cable, and iOS mobile devices using Bluetooth.

### 3.5 Button presses

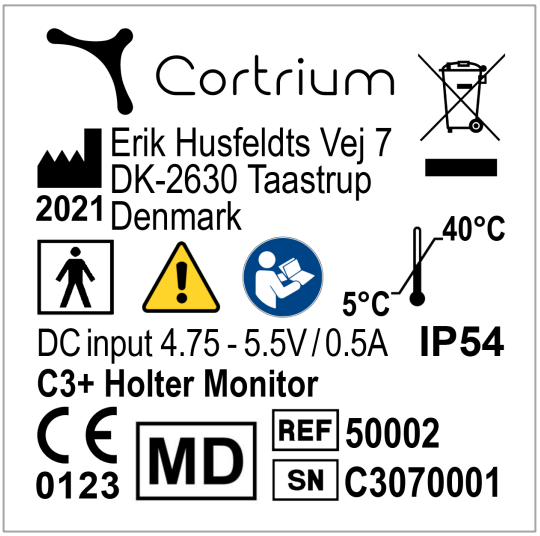
| | Press pattern | Meaning |
|---|---|---|
|  | Single press | Turn on / Mark event |
|  | Double press | Activate Bluetooth |
|  | Long press<br>(3 seconds) | Turn off<br>(Note: Device must not have connection to body) |

### 3.6 LED light notifications

| Color | Light pattern | Meaning |
|---|---|---|
|  <br>Green | Slow:<br>Fast:<br>Constant: | Recording in progress<br>Turning ON / Event button pressed<br>Fully charged |
|  <br>Blue | Slow:<br>Fast: | Streaming Bluetooth<br>Pairing with Bluetooth |
|  <br>Yellow | Slow:<br>Fast:<br>Constant: | Memory full<br>Low battery / Turning off<br>Charging |
|  <br>White | Fast:<br><br>Constant: | Lead OFF detected, C3+ does not have proper contact to body.<br>Error. Contact Cortrium or supplier |

### 3.7 Package and device symbols

The following symbols are found on the C3+ package and device label.




*Device label example*

| Symbol | Description |
|---|---|
|  | Manufacturer and Year of production |
|  | Temperature limitation / temperature range<br><br>5° - 40° degrees Celsius (while operating)<br>-25° - 70° degrees Celsius (while stored) |
|  | Pressure limitation<br><br>700 - 1060 mBar |
|  | Humidity limitation<br><br>10% - 95% |
|  | Serial number (Device ID) |
|  | Reference number |

| | |
|---|---|
|  | Refer to instructions for use |
|  | General warning sign<br>Refer to warning section |
| IP54 | Protected against solid foreign objects<br>(degree 5-dust protected)<br>Protected against ingress of water<br>(degree 4-protected against splashing water from any direction) |
|  | Type BF applied part |
| MD | Medical Device |
|  | Recycle: Electronic equipment |
| CE<br>0123 | CE mark with notified body identification number |
| Cortrium | Company logo with name |

## 4. User instructions

The following section describes how to properly prepare and use the C3+.

### 4.1 Installation of C3+ Cortrium software

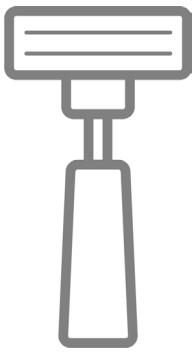
Before using the C3+, download and install the software from www.cortrium.com. When the C3+ is connected to a PC, the device will appear as a Mass Storage Device that can be opened by the software.

### 4.2 How to start a recording

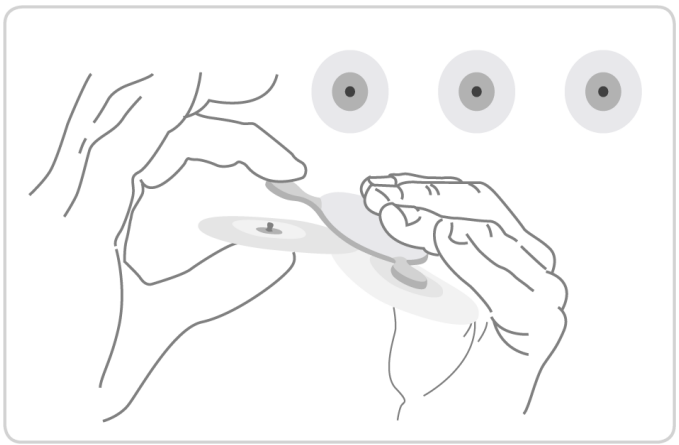
Before starting a new recording, make sure that the C3+ is sufficiently charged as described in section 4.5, and it has been setup for the intended recording using the downloaded software.

**1. Prepare Skin**

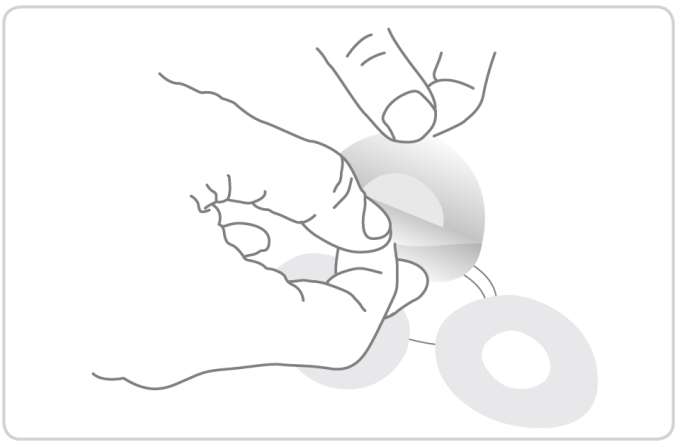
- Shave all hair in the area where the electrodes will be placed.
- Clean and abrade the skin with a cotton swab and appropriate alcohol (denat. 80%).



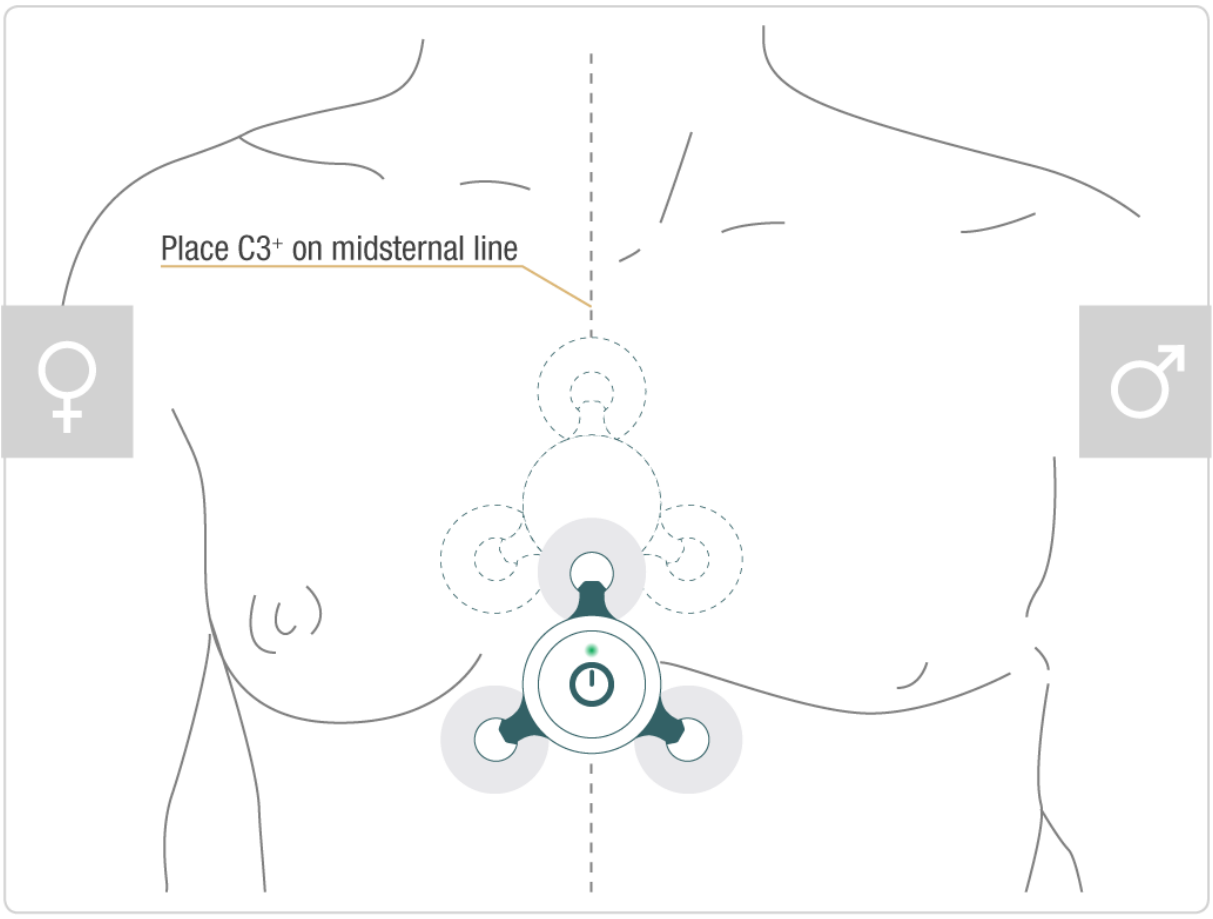
**2. Attach electrodes to each electrode connector**



**3. Remove plastic from electrodes**

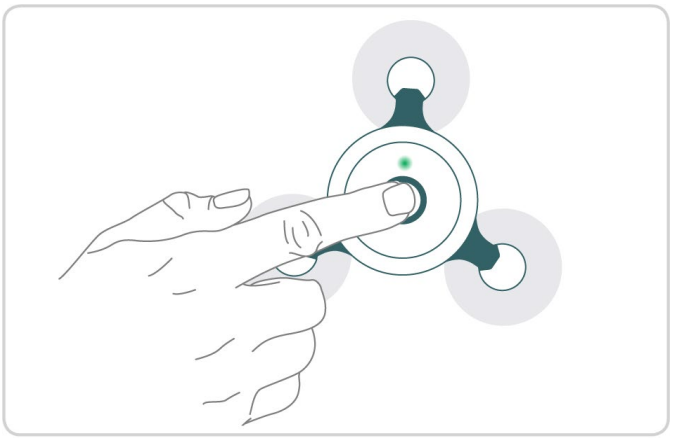


## 4. Attach device to patient




- Make sure the adhesive sticks properly to skin
- Make sure there is no air left between adhesive and skin
- Make sure that there is no hair underneath the electrode
- The dashed outline shows alternative placement of the C3+

## 5. Start Recording



- Press the button
- The green light will flash
- The C3+ is now recording

**4.3 After Use**

1. When recording has ended, remove the device from the patient (patient may have done this already).
2. Detach ECG electrodes, and dispose of them.
3. Connect the C3+ to a PC via USB cable.
4. Extract recordings using Cortriums' software tools.
5. Clean and store the C3+ according to instructions in section 4.5 and 5.2.

**4.4 Charging**

The C3+ automatically charges when connected to a standard USB charger or a PC via the USB cable. The C3+ may charge slower when connected to a PC. NB DC supply voltage 4.75V - 5.5V. Any charger used must be a certified charger complying with IEC 60601-1.

To charge, perform the following actions:

1. Remove any ECG electrodes attached to the C3+.
2. Connect the C3+ to a charger or PC with the USB cable. Never do this while user or patient is in contact with the electrode connectors.
3. Maintain USB connection to the charger or PC until the light indicator turns continuously green.

**4.5 Cleaning**

In order to protect patients against risk of cross-contamination, the C3+ should be cleaned and disinfected in preparation for a new patient (sterilisation is not required).

<u>To Clean</u>

1. Apply a non-abrasive liquid soap to a clean soft cloth.
2. Wipe the C3+ thoroughly.

<u>To Disinfect</u>

3. Apply 70 % isopropyl alcohol to a clean soft cloth.
4. Wipe the C3+ thoroughly.

DO NOT use abrasive cleaners or solvents such as acetone.

### 4.6 Frequently asked questions

1.1. How do I know that the battery of the device is fully charged?

The LED will be continuously green when C3+ is connected to a power source and fully charged.

1.2. Time and date of my measurement were wrong. How can I fix this problem?

The C3+ has an internal clock which compares itself to the clock on the PC, when preparing for a new patient. If the time is incorrect, just setup the device for a new patient, and the device will automatically set the clock to the same time as the PC.

1.3. Do I need software for downloading measurement data from the C3+?

Yes, as a minimum you need the intended software which can be downloaded from www.cortrium.com.

1.4. My C3+ does not start, what might cause this problem?

If the battery is empty, the C3+ will not be able to start. Charge the device using the USB cable and wait for the LED to turn green.

## 5. Maintenance, Storage and Disposal

### 5.1 Maintenance

The C3+ device contains no user serviceable parts, cannot be opened, and does not require routine maintenance. If a problem with the C3+ is experienced, contact Cortrium or your local supplier.

Cortrium service contact:

Cortrium ApS - Erik Husfeldts Vej 7 - DK-2630 Taastrup - Denmark

email: support@cortrium.com - Website: www.cortrium.com

### 5.2 Storage

Do not store the C3+ in locations in which the device would be exposed to:

- Temperatures lower than -25° or greater than 70 ° Celsius
- Air humidity outside 10 - 95 %
- Heavy contamination from dirt or other foreign agents

- Running water
- Strong electromagnetic forces

### 5.3 Warranty

The C3+ has a warranty of 2 years from the date of purchase.

### 5.4 Disposal

The C3+ should be decommissioned when it reaches the end of its service life. The C3+ should be disposed of in accordance with the EU WEEE directive for electronic waste.[1]

## 6. Technical and Regulatory information

### 6.1 Technical specification

| **Technical** | |
|---|---|
| Type of ECG Recorder | Holter, ambulatory ECG |
| No. of Channels | 3 |
| Wear Time | Up to 7 days |
| Recording Format | Continuous |
| Power Requirement | Lithium Polymer, 3.7V, 520 mAh |
| Dimensions | 85 x 80 x 15 mm |
| Weight | 32 grams |
| Sampling Rate | 256 Hz |
| Input Impedance | 10 Mohm |
| Resolution | 24 bit |
| Performance Standard | Design verification IEC 60601-2-47 |
| **Safety** | |
| Safety Standard | IEC 60601-1 Basic Safety & Essential Performance IEC 60601-2-47 |
| **Biological** | |
| Medicinal Substances | N/A |
| Tissue | N/A |
| Body fluids contacted by device | N/A |
| Type of contact to intact skin | Non-invasive |
| Duration of skin contact | Up to 7days continued contact |
| Mucosal membrane contact | N/A |
| Sterile or non-sterile | Non-sterile |
| Biological compatibility | ISO 10993-5<br>ISO 10993-10 |
| **Clinical** | |
| Medical purpose | Ambulatory ECG |

[1] DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE).

| | |
|---|---|
| Single use / reusable | Reusable/Rechargeable Monitor |
| Recording standard | Holter |
| Recording format | Continuous |
| Intended placement | Midsternal line |
| Recording period | Up to 7 days on a single charge |

### 6.2 Regulatory information

The C3+ is a class IIa medical device according to 93/42/EEC. The C3+ complies with the following product standards:

| | |
|---|---|
| DS/EN 60601-1-1 | Safety Requirements for Medical Electrical Systems |
| DS/EN 60601-1-2 | Electromagnetic Disturbances |
| DS/EN 60601-1-6 | Medical Electrical Usability |
| DS/EN 60601-1-11 | Home Healthcare Environment |
| DS/EN 60601-2-47 | Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems |
| DS/EN 62366-1 | Application of usability engineering to medical devices |
| DS/EN ISO 10993-1 | Biological evaluation of medical devices |
| DS/EN ISO 15223-1 | Symbols to be used with medical device labels, labelling and information supplied |
| DS/EN 1041 | Information supplied by the manufacturer of medical devices |
| DS/EN 62304 | Medical device software – software life cycle processes |
| DS/EN ISO 14971 | Application of risk management to medical devices |
| EN 301 489-17 V3.1.1 | Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 17 |
| EN 300 328 V2.1.1 | Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band |

### 6.3 Serious Incidents

In case of serious incidents in relation to the device, please contact your local competent authority as well as Cortrium support@cortrium.com without undue delay.

### 6.4 Declaration of conformity

The C3+ is in conformity with the essential requirements and provisions of the EU Medical Device Regulation (MDR).[2]

[2] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017.

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