Medical device risk classification tool

This summary is for Laptop reading data from heartbeat monito

---

1. What type of medical device are you registering?

General medical device

2. Does the device have an integral part which is a registrable medicine (therapeutic product) that only functions to act on the human body with action ancillary to that of the device?

Examples: bone cements with antibiotic, wound dressings incorporating antimicrobial agents to provide ancillary action on the wound

No

3. The device was manufactured from or has incorporated any of the following:

- ○ Derivatives of cells or tissues of human origin, rendered non-viable
- ○ Cells, tissues or their derivatives of animal origin (rendered non-viable) or recombinant origin
- ✓ **None of the above**

4. What is the intended use of the device.

- ○ Sterilise or disinfect medical devices (including contact lenses), or hydrating contact lenses
- ○ Contraceptive or used to prevent the transmission of sexually transmitted diseases
- ✓ **None of the above**

5. Is the device invasive?

No

6. Is the device an active medical device?

No

7. Is the device non-invasive?

Yes

8. Does the non-invasive device come into contact with injured skin?

No

9. Is the non-invasive device intended to modify the biological or chemical composition of blood, body liquids, or other liquids, for infusion into the body?

No

10. Is the non-invasive device intended for channelling or storing body liquids, tissues, liquids or gases for eventual infusion, administration or introduction into the body?

No

Your device's risk classification is Class A.

Examples: urine collection bottles, compression hosiery, non-invasive electrodes, hospital beds.

The risk classification above is based on GN13 rule 4.

To continue registering your medical device, you may check the registration and licensing requirements for your device.