

## Device Schedule: Class III and Class IIb devices

| <b>Class III</b>  | <b>Intended purpose</b> |
|---|-------------------------|
| External temporary cardiac stimulators dual chamber                     | See MDR 823996          |
| External temporary cardiac stimulators single chamber                   |                         |
| MYOPACE® - epimyocardial pacing wires for temporary cardiac stimulation | See MDR 747885          |
| Endocardial Leads for Temporary Pacing and Electrophysiological Studies | See MDR 823997          |

  

| <b>Class IIb</b>  | <b>Intended purpose</b>   |
|---|---|
| Esophageal temperature monitoring system, including sterile probes and connecting cables. | Intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms.  |
| External cardioversion defibrillation electrode pads.                                     | Disposable multifunction electrodes intended for: <ul style="list-style-type: none"><li>- Transthoracic external defibrillation.</li><li>- Transthoracic synchronized cardioversion.</li><li>- Transthoracic ECG Monitoring.</li><li>- Temporary transthoracic cardiac pacing (non-invasive).</li></ul> |
| Single use surgical instruments and neutral electrodes for use in electrosurgery.         | Single use, sterile and non-sterile, handpieces and electrodes, including grounding plates, intended for cutting and coagulation of soft tissues, when used in conjunction with a compatible high-frequency generator, in monopolar electrosurgical procedures.   |
| Reusable surgical instruments and neutral electrodes for use in electrosurgery.           | Reusable handpieces and electrodes, including grounding plates, intended for cutting and coagulation of soft tissues, when used in conjunction with a compatible high-frequency generator, in monopolar electrosurgical procedures.   |

## Device Schedule: Class III and Class IIb devices

| <b>Class IIb</b>                      | <b>Intended purpose</b>   |
|---------------------------------------|---|
| Instruments for diathermocoagulation. | Reusable and sterile single-use handpieces and electrodes, intended for cauterisation of soft tissues and small blood vessels in surgical procedures. |

## Device Schedule: Class IIa, Custom-made and other devices

| <b>Device(s)</b>                                  | <b>Risk Classification</b> |
|---|----------------------------|
| Accessories for oxygentherapy and aerosoltherapy. | Class IIa                  |
| Transesophageal arrhythmology devices.            | Class IIa                  |
| Cardiocirculatory introducers                     | Class IIa                  |
| Non implantable cardiac stimulators – hardware    | Class Is                   |
| Cleaning pads and holsters for electrosurgery     | Class Is                   |
| Accessory for percutaneous dilator sheaths        | Class Is                   |

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.