**Appendix 8.2.2 Overall biological safety assessment**

**1 Product Description**

***【添加产品的描述，同时可用结构图示进行描述。】***

**2 Intended use**

***【添加产品预期用途。】***

**3 Materials incorporated into key functional elements**

A description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body is as below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Model*** | ***Components*** | ***Contact Method*** | ***Contact position*** | ***Materials*** | ***Supplier*** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |
| ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** | ***\*\*\**** |

**4 Evaluation Procedures**

4.1 Is it in direct or indirect contact?

***{【产品名称】 is used to directly contact with the patient’s skin.***

***According to EN ISO 10993-1, medical device is categorized by nature of contact and duration of contact.***

***As the categorization by nature of body contact, surface-contacting devices shall be categorized according to their contact with the following application sites:***

1. ***Skin***

***- devices that contact intact skin surfaces only.***

***Examples Electrodes, external prostheses, fixation tapes, compression bandages and monitors of various types.***

1. ***Mucosal membranes***

***- devices that contact intact mucosal membranes.***

***Examples Contact lenses, urinary catheters, intravaginal and intra-intestinal devices(stomach tubes, sigmoidoscopes, colonosopes, gastroscopes), endotracheal tubes, bronchoscopes, some dental prostheses and orthodontic devices.***

1. ***Breached or compromised surfaces***

***- devices that contact breached or otherwise compromised body surfaces.***

***Examples Dressings or healing devices and occlusive patches, for ulcers, burns and granulation tissue.***

***As the categorization by duration of contact, devices whose cumulative single, multiple or repeated long-term use or contact is likely exceed 24 h but not 30d.***

***So, the 【产品名称】 is a Surface contacting, Prolonged exposure device.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***SN*** | ***Model*** | ***Contact with human body*** | ***Contact Method*** | ***Contact classification*** |
| ***Category*** | ***Contact Duration*** |
| ***1*** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** |
| ***2*** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** |

***}***

3.2 Obtain material identification information and consider chemical characterization

The material information of ***【产品名称】*** that contact with the patients is as below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Model | Components | Contact method | Contact position | Materials | Supplier |
| ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** |
| ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** |
| ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** |
| ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** |
| ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** | ***\*\*\*\**** |

3.3 Is the material the same as a commercially available device?

***(Yes, the material is the same as a commercially available device. The materials have been used by many Reusable temperature probes those market in European. So we consider the material is the same as commercially available device.)***

3.4 Does the device have the same chemical composition

***(Yes, the device have the same chemical composition. The details of description can refer to section 3.2.)***

3.5 Are manufacturing and sterilization the same?

***(Yes, the manufacturing and sterilization are the same. The details of description can refer to section 3.2.)***

3.6 Is the body contact the same?

***(Yes, the body contact is the same. The intended use of the 【产品名称】 does not changed.)***

3.7 Perform biological evaluation according to Annex A in the EN ISO 10993-1:2020

***(The 【产品名称】 is a Surface contacting, Prolonged exposure device. According to Annex A in the EN ISO 10993-1:2020, the Cytotoxicity, Sensitization and irritation or intracutaneous reactivity should be considered.)***

The details of tests carried out are as follows.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***SN*** | ***Product*** | ***Test basic*** | ***Test Item*** | ***Report number*** | ***Test result*** |
| ***1*** | ***\*\*\**** | ***ISO 10993-5***  | ***Test for in vitro cytotoxicity***  | ***Report No.: \*\*\**** | ***PASS*** |
| ***ISO 10993-10*** | ***Test for skin sensitization*** | ***Report No.: \*\*\**** | ***PASS*** |
| ***ISO 10993-10*** | ***Test for irritation (intracutaneous reactivity test)*** | ***Report No.: \*\*\**** | ***PASS*** |

3.8 Biological evaluation completed

After evaluation, the biocompatibility of the accessories of ***【产品名称】*** was in line with the expected use and regulatory requirements. All the risks related with biological are acceptable and under control.

**4 Conclusions**

***Through the above analysis of biocompatibility, all the biological risks are acceptable and under control. The 【产品名称】 meets the requirement of EN ISO10993-1:2020 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process.***