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1.0 Purpose

The purpose of this document is to perform a biological evaluation of Hearlab according to Annex B of ISO 10993-1: 2003.

2.0 Evaluation

- 2.1 Does the device contact the body directly or indirectly? Yes: The electrodes, electrode sensors, material used for preparing for test, and the electrode cords all have contact with the patient.
- 2.2 Is the material the same as in an existing commercially available device? Yes, all parts that have contact with the patient are available in existing commercial devices.
- 2.3 Does the device have the same properties as in commercially available devices? Yes, the materials that have contact with the patient are used in the same way as with existing commercially available devices. None of these materials is considered sterile. The clinician is advised not to reuse the sensor pads.
- 2.4 Final assessment: All parts are used in existing medical devices. The sensor pads and preparation material, in particular, are the same as used in existing equipment and used in exactly the same way on Hearlab. All Hearlab tests are performed in less than an hour making all contact transitory in nature. Therefore, the material identified in this document meets the requirements of ISO 10993-1.