Declaration of conformity for special requests of prosthetic components

in accordance with MDD 93/42/EEC Appendix VIII

Basic Requirements in accordance with MDD 93/42/EEC Annex I
The following list specifies the Basic Requirements in accordance with MDD 93/42/EEC Annex I, which are met for special requests of prosthetic components. Inapplicable, unfulfilled or unverified Basic Requirements are listed with corresponding explanations.

I. General requirements

1. **Unverified:** Clinical condition, safety and health of the patient and the user has not been verified.
   Grounds: The device was specifically designed by the customer for the patient listed and cannot be influenced or verified by Cendres+Métaux. Cendres+Métaux guarantees the material and fabrication. **Responsibility with regard to device design of this custom fabrication lies with the customer.** For comparable CE-marked devices, however, clinical reviews have been documented by Cendres+Métaux, which verify the safety and health of the patient and user.
2. **Complied with:** Hazards and risks have been and will be reviewed as part of the risk management process. Risks have been eliminated or reduced, protective measures taken and residual risks specified in the user documentation.
3. **Complied with:** The device characteristics have been specifically designed by the customer for the patient listed. Device design: See explanation of Para. 1. Fabrication and packaging: Processes have been reviewed and are approved.
4. **Unverified:** Grounds, see explanation of Para. 3.
5. **Complied with:** Grounds, see explanation of Para. 3.
6. **Unverified:** Grounds, see explanation of Para. 1.

6a **Unverified:** Grounds, see explanation of Para. 14.

II. Requirements for the design and engineering

7. Chemical, physical and biological properties

7.1 **Complied with:** Only tested and approved materials are used.
7.2 **Complied with:** Device design: See explanation of Para. 1. The fabrication and packaging of this custom-made device has been carried out in accordance with standardized QA workflows similar to standard devices, i.e. all precautions to protect the health and safety of the patient and user have been taken by Cendres+Métaux.
7.3 **Unverified:** Grounds, see explanation of Para. 7.2.
7.4 **Not applicable:** Not a drug.
7.5 **Not applicable:** Devices contain no substances.
7.6 **Unverified:** Grounds, see explanation of Para. 7.2.

8. Infection and microbial contamination

8.1 **Complied with:** Grounds, see explanation of Para. 2.
8.2 **Not applicable:** No tissue of animal origin.
8.3 **Not applicable:** Device is not delivered sterile.
8.4 **Not applicable:** Device is not delivered sterile.
8.5 **Complied with:** Sterilizability of the device is ensured.
8.6 **Complied with:** The device packaging is approved for its intended use (packaging is not sterilized).
8.7 **Not applicable:** Device is not provided sterile and non-sterile at the same time.

9. Properties in terms of design and environmental conditions

9.1 **Unverified:** Grounds, see explanation of Para. 7.2.
9.2 **Complied with:** Grounds, see explanation of Para. 2.
9.3 **Not applicable:** Device is not flammable and contains no oxidizing substances.

10. Devices with measuring function

10.1 to 10.3 Not applicable: Device has no measuring function.

11. Protection against radiation

11.1 to 11.5 Not applicable: Device is not designed for emitting radiation. Radiation exposure of people and patient is not possible.

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12. Requirements for devices with external or internal energy source

12.1 to 12.6 **Not applicable:** Device has no internal or external source of energy or electronic systems.
12.7.1 **Complied with:** Each sales unit is checked for proper fit and mechanical stability.
12.7.2 **Not applicable:** Device generates no mechanical vibrations.
12.7.3 **Not applicable:** Device generates no sound.
12.7.4 **Not applicable:** Device contains no connections to sources of energy.
12.7.5 **Not applicable:** Device does not emit heat.
12.8.1 **Not applicable:** Device does not emit energy or materials.
12.8.2 **Not applicable:** Device contains no volume control.
12.9 **Not applicable:** Device does not contain any operating and display device.

13. Supply of information by the manufacturer

13.1 **Complied with:** There is user documentation for this custom fabrication.
13.2 **Complied with:** Label according to EN 980 and ISO 15223-1 (proof of labeling instructions).
13.3a **Complied with:** See label.
13.3b **Complied with:** See label.
13.3c **Not applicable:** Device is not delivered sterile.
13.3d **Complied with:** See label.
13.3e **Not applicable:** No expiration date necessary.
13.3f **Complied with:** See label.
13.3g **Complied with:** See label.
13.3h **Not applicable:** Device is not intended for clinical testing.
13.3i **Not applicable:** No special storage or handling required.
13.3j **Complied with:** See user documentation.
13.3k **Complied with:** See user documentation.
13.3l **Not applicable:** No active device.
13.3m **Complied with:** See user documentation.
13.3n **Not applicable:** No components of human blood.
13.4 **Complied with:** See user documentation.
13.5 **Complied with:** Special number on labeling.
13.6a **Complied with:** See 13.3
13.6b **Unverified:** The device performance data is interpreted by the customer. General details are described in the user documentation.
13.6c **Complied with:** See user documentation.
13.6d **Complied with:** See user documentation.
13.6e **Not applicable:** Devices are not implanted.
13.6f **Not applicable:** Device is not used for special studies or treatment methods.
13.6g **Not applicable:** Device is not delivered sterile.
13.6h **Not applicable:** Device is not intended for reuse.
13.6i **Complied with:** See user documentation.
13.6j **Not applicable:** See Para. 11.1 to 11.5.
13.6k **Unverified:** Grounds, see explanation of Para. 3.
13.6l **Not applicable:** See Para. 12.
13.6m **Not applicable:** Not a drug.
13.6n **Not applicable:** No hazardous waste.
13.6o **Not applicable:** Not a drug.
13.6p **Not applicable:** No measuring device.
13.6q **Complied with:** See user documentation.

14. Clinical data

Unverified: No clinical data has been collected. Grounds: The fabrication listed is a custom-made device specifically defined by the customer for the patient listed and fabricated by Cendres+Métaux.