

Doc. name	Issue	Doc. No.
Certificate of Compliance	07	REC-012

Manufacturer	Blomdahl Medical AB Olofsdalsvägen 45 S-302 41Halmstad, Sweden
Products	Blomdahl Medical Ear Piercing Blomdahl Medical Nose Piercing Blomdahl Skin Friendly Jewellery

Blomdahl Medical AB develops, manufactures and markets medical piercing products and skin friendly jewellery.

In U.S.A. our ear piercing products are classified as medical devices class I and are listed with the FDA (Food & Drug Administration). Blomdahl Medical AB is an FDA registered manufacturer.

According to present EU legislation piercing products and jewellery are not classified as Medical Devices. Due to our products being surgically invasive and/or coming into long-term contact with the skin, we have decided to follow all critical parts of the regulations applicable for sterile medical devices, in addition to the regulations applicable for jewellery. For example, our piercing products are:

- assembled and packed in a controlled environment (clean-room),
- packed, sterilized and labelled according to standards which are harmonized with the MDD (EU Medical Device Directive),
- the materials in the products have been chosen with respect to their biocompatibility and non-toxicity.

We hereby assure that our piercing products are manufactured under compliance of ISO 13485 (quality system used by medical device manufacturers all over the world).

We hereby assure that our medical piercing products are sterilized in accordance with ISO-11135 (the world-wide standard within the medical device industry for EO sterilization).

We hereby assure that our skin friendly jewellery and medical piercing jewellery comply with the limits for nickel, cadmium and lead as stipulated by REACH regulation, Annex XVII, (entry 23, 27 and 63) regulation (EC) no 1907/2006 about Registration, Evaluation, Authorization and Restriction of Chemicals. In many aspects we have gone further than required by the regulations, i.e. the nickel content and/or the nickel release is 0 % or so close to 0 % that our jewellery cannot cause nickel allergy.

We hereby assure that our Medical Plastic jewellery - all parts coming into long-term contact with the skin - are of medical grade and comply with applicable requirements of ISO 10993 and/or USP XXIII Class VI (International and American standards for biological evaluation of medical devices).

We hereby assure that our Titanium earrings and nose jewellery - all parts coming into long-term contact with the skin - are made of pure medical grade titanium as stipulated by ISO 5832-2 and/or ASTM F67 (International and American standards for non-alloyed titanium for use in implants).

We hereby assure that our Titanium rings - all parts coming into long-term contact with the skin - are made of medical grade titanium as stipulated by ISO 5832-3 and/or ASTM F136 (International and American standards for alloyed titanium for use in implants), and that our bracelets and necklaces have a skin friendly ceramic coating.

Halmstad / Sweden, May 16th 2019



Kristina Sandström, QA