

## Declaration of Conformity

We, the above named company Lewa-Dental, declare with sole responsibility, that the following medical devices (class IIa)

- Palatal Expansion Screws

to which this declaration refers, fulfil the requirements of following guideline:

**Council Directive 93/42/EEC of 14. June 1993 concerning medical devices**

In this regard, Lewa-Dental Feinmechanik GmbH & Co. KG has introduced a Quality-Management System which is certified in accordance and DIN EN ISO 13485:2012 and which fulfils the requirements of directive 93/42/EEC and 2007/47/EEC for medical devices, appendix II.

Notified body: mdc GmbH. Kriegerstr.6 70191 Stuttgart, CE 0483

D - 75196 Remchingen, 2017-06-20



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Frank Lemmermeier  
( General Manager )