

Declaration of conformity

Report No.UPQ/JZ-42-0032-2013

- Manufacturer: Liaoning Upcera Co.,Ltd
- Address: No.122 Xianghuai Road, Economic Development Zone, Benxi ,Liaoning ,P.R.C.
- European Representative: MEDNET GmbH
- DIMDI Code: DE/0000012115
- Product: Zirconia Dental Ceramics
- Specification/Models: refer to Zirconia Dental Ceramics--- CE technical file.
- Classification: Class II a, Rules 8, ANNEX V, MDD

We declare under our sole responsibility that the above mentioned product meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

Standards:

EN ISO14971 2009

EN ISO 10993-1:2009

EN ISO10993-3:2003

EN ISO10993-5 2009

EN ISO10993-10 2009

EN ISO10993-11 2009

EN980 2008

EN1041 2008

EN 1641 2004

ISO 13485 2012/AC2009

ISO7405 2008

ISO6872 2008

ISO 13356 2008

YZB/Liao 0845-2010

All applicable harmonized standards(published in the official journal of the European Communities)

Directives: General applicable directives: Medical device Directive MDD 93/42/EEC

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

2007/47/EC

Conformity assessment moduels: Annex V

Notified Body: TUV 0197