Kerr™

EC-Declaration of Conformity

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Manufacturer: **Kerr Corporation - 1717 West Collins Avenue, Orange, CA 92867, USA**

Manufacturing Site: **PLEXUS XIAMEN CO LTD - (Xiamen1), No 6 Xiangxing 2 Road, Modern Logistics Zone, Xiamen, Fugian Province 361006, CN**

EU Auth. Representative: **Kerr Italia S.r.l. - Via Passanti, 332 I-84018 Scafati (SA), Italy**

Object(s) of the Declaration: **Demi Ultra**

Part Number(s): **35664 / 35665 / 35666 / 35667 / 35668 / 35815 / 35837**

Route to Compliance: **Annex VII of MDD 93/42/EEC, amended by 2007/47/EC**

Classification: **Class I according Annex IX of directive 93/42/EEC**

The object(s) of the declaration described above is in conformity with the requirements of the following documents:

Document No.	Title
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN 1640:2009	Dentistry – Medical devices for dentistry – Equipment
BS EN ISO 9687:1996	Dental Equipment – Graphical Symbols
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation & Testing
EN ISO 13485:2003	Medical devices - Quality management systems
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects – Good Clinical Practice
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
ISO 15223-1:2012	Medical devices. Symbols to be used with medical device labels, labeling, and information to be supplied. Part 1: General requirements
EN 60601-1:2006	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and Tests
PD IEC/TR 62471-2:2009	Photobiological safety of lamps and lamp systems
EN 62304:2006	Medical Device Software - Software life-cycle processes
EN 62366:2008	Medical Devices - Application of Usability Engineering to Medical Devices

Kerr Corporation declares that the above mentioned object(s) meets the provision of the Council Directive 93/42/EEC as amended by 2007/47/EC for Medical Devices. Kerr Corporation is the natural and legal organization with responsibility for the design, manufacture, packaging, and labeling before the object is placed on the market under the Kerr Corporation name.

Date: September 18, 2013

Scafford Serron

Dr. Scafford Serron/Kerr VP of Quality Assurance