Avda. La Ferreria, 62 (Pol.Ind. La Ferreria)
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Phone: 935 646 491
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DECLARATION OF CONFORMITY – CUSTOM ABUTMENTS

PRODUCTS:	Customized Titanium Abutments
INTENDED USE:	In dental laboratory: • They are part of the final prosthetic restoration in conjunction with the implant and prosthetic unitary crown or bridge pillar.

PRODUCTS:	Customized Cobalt-Chrome Abutments
INTENDED USE:	In dental laboratory: • They are part of the final restoration as a support for ceramic or composite veneering in single crowns. Those crowns are directly screwed into implant.

PRODUCTS:	Customized Zirconium Oxide Abutments
INTENDED USE:	In dental laboratory: • They are part of the final restoration in conjunction with the implant and prosthetic unitary crown or bridge pillar; Can be used either as support for ceramic veneering (depends on its morphology).

THE CONFORMITY ASSESSMENT PROCEDURE UNDER DIRECTIVE 93/42/EEC (as amended by 2007/47/EC):	Annex V
THE CONFORMITY ASSESSMENT PROCEDURE UNDER ROYAL DECREE 1591/2009, of October 16th:	Annex VIII Annex I

Hereby, DESS LAB TERRATS MEDICAL, SL declares that the mentioned products fulfils the essential requirements set out in the Annex I and Annex VIII of Royal Decree 1591/2009, of October 16th, that regulates medical devices and in the Annex V of Directive 93/42/EEC (as amended by Directive 2007/47/EC) - excluding the design and in vitro, and the essential requirements of the following harmonised standards:

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- EN 15223-1:2013 (*Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements*)
- EN 1041:2009+A1:2014 (*Information supplied by the manufacturer with medical devices*)
- EN 1641:2010 (*Dentistry - Medical devices for dentistry - Materials*)
- EN ISO 10993-10:2013 (*Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity*)
- EN ISO 10993-15:2009 (*Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys*)
- EN ISO 14971:2012 (*Medical devices - Application of risk management to medical devices (ISO 14971:2007*)
- EN ISO 10993-18:2009 (*Biological evaluation of medical devices - Part 18: Chemical characterization of materials)*
- EN ISO 13485:2012 (*Medical devices - Quality management systems - Requirements for regulatory purposes*)
- ISO 5832-3:2012 *(Implants for surgery –metallic materials- part 3: wrought titanium 6-aluminium 4-vanadium alloy)*
- ISO 5832-12:2007 *(Implants for surgery – metallic materials – part 12: wrought cobalt-chromium-molybdenum alloy)*
- EN 62366:2009 (*Medical devices – Application of usability engineering to medical devices*)
- EN ISO 13356:2013 *(Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia)*

Montcada i Reixac, 4th of September 2015

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Mr. Jordi Terrats Bes

General Manager