

ACEONEDENT KOREA INDUSTRIAL COMPANY	Technical Construction File	No. of Document	ADK-T-02-11
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EC Declaration of Conformity

ORIGINAL

Report No : ADK-T-02-11(Rev.11)

Prepared by : 이희희

Date : Feb 27 ,2015

Signatory : 김희림

Date : Feb 27 ,2015

Position : 품질관리

Signatory : 조아라

Date : Feb 27 ,2015

Position : 관리부

Signatory : 장기훈

Date : Feb 27 ,2015

Position : 생산관리

Signatory : 윤찬미

Date : Feb 27 ,2015

Position : 해외영업부

Signatory : 오성호

Date : Feb 27 ,2015

Position :

Signatory :

Date : Feb 27 ,2015

Position :

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EC Declaration of Conformity

In accordance with EC directives 93/42/EEC and 2007/47/EC relating to Medical Devices.

We herewith declare that the under-mentioned device, in view of its design and type of construction, meets the requirements of the above EC Directive.

If the device is modified without the agreement of the undersigned, this declaration becomes invalid.

Product : 1.Dental Root-Canal Obturating Points ,
2.Dental Absorbent points
3.Gutta Percha Points cutter
4.Poly vimyl siloxane Impression Material
5.Endo Gauge

Model Name : 1.Gutta Percha Points (Class IIa)
2.Absorbent paper points (Class IIa)
3.G/P Trimmer (TR-201) (Class I)
4.ACE-SIL (Class I)
5.GP CUT

Relevant EC Directives : Medical Device Directive 93/42/EEC and 2007/47/EC

is subject to the procedure set out in Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Limited, Unit 202 B, Worle Parkway, Weston-Super-Mare, Somerset, BS22 0WA United Kingdom.

APPLICABLE NORMATIVE REFERENCES

- 1) Council Directive 93/42/EEC and 2007/47/EC
- 2) EN ISO 14971 [20012] Medical devices Application of risk management to medical devices
- 3) EN ISO 1041 [2008] Information supplied by the manufacturer with medical devices
- 4) EN ISO 980 [2008] Graphical symbols for use in the labeling of medical devices
- 5) ISO 9001[2008] Quality systems - Model for quality assurance in design, development, production, installation and servicing
- 6) ISO 13485 [2003] Quality systems - Particular requirements for the application of ISO 9001
- 7) ISO 6877 [2006] Dentistry - Root-canal obturating points
- 8) ADA - ANSI/ADA Specification no. 57 for Endodontic Filling Materials.
- 9) ISO 1641 [2009] Dentistry - Medical devices for dentistry - Materials

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Representative harmonised standard (eg. ISO6877, ADA)

ORIGINAL

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Manufacturers Registered Name : Aceonedent Korea Industrial Company

Manufacturers Registered Address : 103-606, Bucheon Techno-Park, 22, Samjak-ro,
Ojeong-gu, Bucheon-si, Gyeonggi-do, Korea

Date: Feb. 27, 2015

Sung-Sik Lee/CEO

