



SAESHIN PRECISION CO., LTD.
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EC Declaration of Conformity

TRAUS ENDO series("Dia-Gear" series) have been classified as Class II a (Annex IX Rule 9) and are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by Directive 2007/47/EC

Manufacturer: SAESHIN PRECISION CO., LTD.

#52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun, Daegu, Korea

Declare that the medical devices described hereafter

| | |
|---|---|
| Product Name | TRAUS ENDO Series("Dia-Gear" series): Power unit (TRAUS MCE10XX, Dia-Gear Handpiece), Charging station (TRAUS XEW10, Dia-Gear Charger) Hand-piece (ACL(B)-41EP, ACL(B)-42EP, ACL(B)-45EP, Dia-Gear Angle) |
| Intended Use | Intra-oral use for dental cutting, polishing, grinding, drilling and endodontic treatment (with power units) |
| MDD Classification | Class IIa |
| Harmonized and other applicable standards | EN ISO 13485, EN ISO 14971, EN 1041, EN ISO 15223-1, EN 980, EN ISO 9687, EN ISO 17664, EN ISO 17665-1, CEN ISO/TS 17665-2, EN ISO 11138-1, EN ISO 11138-3, EN ISO 11737-1, EN ISO 11737-2, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN 62304, EN 80601-2-60, EN 1640, EN ISO 7494-1, EN ISO 7405, EN 62366, EN ISO 14457, EN ISO 1797-1, ISO 3964, EN ISO 1942, EN 60601-1, EN 60601-1-2, EN 60601-1-6 |

TRAUS ENDO series("Dia-Gear" series) are subject to the procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body SGS Yarsely International Certification Services Limited Unit 202B, Worle Parkway, Weston-Super-Mare, North Somerset, BS 22 OWA, United Kingdom

Place. Date of issue : Korea / 01 September 2016

EC certificate : KR98/13778

Start of CE-marking : 06 August 1998

EC Authorised Representative

Dongbang Acuprime

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President

on behalf of SAESHIN PRECISION CO., LTD