# EC Certificate

TÜVRheinland®

**Production Quality Assurance**
**Directive 93/42/EEC on Medical Devices, Annex V**

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| Registration No.: | DD 2110503-1 |
| Manufacturer: | Dongguan Kaiser Technology Co., Ltd.<br>No.6, 2nd Road, Sanjiang Industrial Block,<br>Hengli Town, Dongguan City,<br>523462 Guangdong<br>P.R. China |
| Products: | Bone Drills (machine only), Orthopedic Reamers (machine only), Electrical Surgical Bone Saws (machine only), Surgical Lavage Units, Surgical Illuminators, Bone Cement Mixer Syringe, Warming and Cooling Therapy, Blanket Warming Units;<br>Aspects of manufacture concerned with securing and maintaining sterile conditions: Bone Cement Mixer, Torque Instruments Manual |

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

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| Report No.: | 10918671-100 |
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| Expiry date: | 2024-05-26 |
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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



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