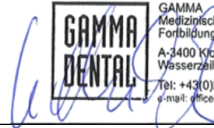



Clarification Regarding Quality Management System Certification

We hereby confirm that, as a **manufacturer of medical devices**, our quality management system is fully certified in accordance with **EN ISO 13485 – Quality Management Systems for Medical Devices**, as evidenced by the certificate previously provided.

EN ISO 13485 is the internationally recognized standard specifically designed for medical device manufacturers. It encompasses all requirements for quality management, regulatory compliance, and product safety throughout the entire lifecycle of medical devices. Our **EN ISO 13485 certification** ensures full compliance with all applicable regulatory and quality requirements for the manufacturing of medical devices.

GAMMA
Medizinisch-wissenschaftliche
Fortbildungs-GmbH

By:  
Christian Slavicek

GAMMA
Medizinisch-wissenschaftliche
Fortbildungs-GmbH
A-3400 Klosterneuburg
Wasserzeile 35
Tel: +43(0)2243/341 40
e-mail: office@gammadental.com