

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

GC Orthodontics Europe GmbH
Harkortstraße 2
58339 Breckerfeld
Germany

Holds Certificate Number:

MD 593588

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture and sales of non-sterile orthodontic devices and accessories
Produktion und Vertrieb von unsterilen kieferorthopädischen Produkten und Zubehör

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-05-25

Latest Revision Date: 2021-10-18

Effective Date: 2021-10-20

Expiry Date: 2024-10-19

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