

EC Certificate Directive 93/42/EEC Annex V **Production Quality Assurance** Medical Devices

Registration No.: DD 60138765 0001

Report No.:

15069263 009

Manufacturer:

OSAKADENT GROUP LIMITED Unit 04,7/F,Bright Way Tower

NO.33 Mong Kok Road Kowloon, HK

Products:

Sterile Absorbent Paper Points and Gutta Percha Points

Expiry Date:

2025-05-26

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.

Effective Date:

2021-12-31

Date:

2021-12-31

Notified Body

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TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.