

# EC DECLARATION OF CONFORMITY

According to ISO/IEC 17050-1: 2004 (Supplier's DOC) & ISO/IEC 17050-2: 2004(Supporting Document Supplier's DOC)

## European Union

Conformité Européene

**Registration Information:** DNV GL PRESAFE AS NB: 2460  
CE: 241962-2017-CE-NOR-NA-PS Rev.1.0  
Valid: 27.05.2024

**Route to Compliance:** The conformity assessment procedure described in Annex II Excluding section 4 of Council Directive of 93/42/EEC on medical devices, as amended.

**Manufacturer:** Saga Dental Supply AS  
Øvre Langelandsvn.19  
2213 Kongsvinger  
Norway  
Tel: +4762814898

**Manufacturer SRN:** NO-MF-000001425

**GMDN Code:** 31754

**General Product Name:** Rotation wedge

**Intended use:** Labial Rotation Wedge is used to rotate the teeth while using twin or single brackets in the maxillary or mandibular arch.

## Product Trade Name:

TRADE NAME	REF
ROTATION WEDGE - LARGE	10029
ROTATION WEDGE - CLEAR, MEDIUM	10024
ROTATION WEDGE - CLEAR, SMALL	10023
ROTATION WEDGE - GREY, MEDIUM	10026

ROTATION WEDGE - GREY, SMALL	10025
ROTATION WEDGE - SILVER, MEDIUM	10028
ROTATION WEDGE - SILVER, SMALL	10027

We, Saga Dental Supply AS of Kongsvinger, Norway, declare with our sole responsibility that the products listed above meet the essential requirements of the Council Directive 93/42/EEC, as amended by 2007/47/EC, pertaining to Medical Devices.

Products referenced herein are marked with CE marking according to the specified directive with applied standards ISO 13485, ISO 15223-1 and ISO 14971.

### **Where indicated and applied**

This document expires on 27.05.2024

Signed this on the behalf of Saga Dental Supply AS by

*Swadesh Kumar*

Dr. Swadesh Kumar BDS, D. Orth  
MD