

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: 38741

General Product Name: Saga Mini Lock w/wo hooks

Intended use: Arch wire stop used as anchorage, activation, or for prevention of wire migration during orthodontic treatment. Used as a lock on orthodontic wires for moving for stopping other orthodontic appliances

Product Trade Name:

TRADE NAME	REF
MINI LOCK COMPLETE STANDARD	08049
MINI LOCK COMPLETE W/ HOOK	08050

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
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