

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: Arch wire stops, Arch wire hooks, Surgical ball hooks or hooks.

Intended use: 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:

NAME	REF
SURGICAL BALL HOOK 400-018 R	12041
SURGICAL BALL HOOK 400-022 R	12045
SURGICAL BALL HOOK 401-018 L	12043

SURGICAL BALL HOOK 401-022 L	12047
SURGICAL BALL HOOK 402-018	12049
SURGICAL BALL HOOK 402-022	12051
SURGICAL BALL HOOK 404-022/050	12080
SURGICAL BALL HOOK 404-030	12087
SURGICAL BALL HOOK 404-036	12088
SURGICAL BALL HOOK 405-018	12053
SURGICAL BALL HOOK 405-022	12055
SURGICAL BALL HOOK 406-018	12057
SURGICAL BALL HOOK 406-022	12059

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