

# 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:** 41678

**General Product Name:** Mandibular Locking Unit (MALU)

**Intended use:** Correction of the malocclusion used by dentist or orthodontist

## Product Trade Name:

TRADE NAME	REF
Version 1 standard Malu set 32 mm long 1.1 mm ball pin	07999
Version 1 standard Malu set 32 mm long 1.2 mm ball pin	08000
Version 1 standard Malu set 32 mm long type 2 silver solder	08019
Version 2 pre cut Malu set 1.1 mm ball pin	08001
Version 2 pre cut Malu set 1.2 mm ball pin	08061

Version 3 fixed Malu set 1.2 mm ball pin	08023
Version 3 fixed Malu set 1.1 mm ball pin	08036
Malu set sundsvall	08002
Malu elastic jumper	08070
Malu spring jumper	08080
Malu tubular jumper	08055

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