

# 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

<b>Registration Information:</b>	Self-Certified Annex VII Council Directive 93/42/EEC, as amended by 2007/47/EC Medical Devices
<b>Device:</b>	Class I Non-Invasive devices, Transient Use 93/42/EEC, Annex IX, Sterilize before use.
<b>Route to Compliance:</b>	Annex VII
<b>Manufacturer:</b>	<i>SAGA DENTAL SUPPLY AS</i> Øvre Langelandsvn.19 2213 Kongsvinger Norway Tel: +4762814898
<b>Manufacturer SRN:</b>	NO-MF-000001425
<b>GMDN Code:</b>	13380
<b>General Product Name:</b>	Lip & Cheek retractors
<b>Intended use:</b>	Isolation for bonding, bleaching of teeth & photography of oral cavity.
<b>Product Trade Name:</b>	Scandee Small, Medium & Large PC Clear Scandee Small, Medium & Large PC Colored Scandee Small, Medium PP Opaque Scandee Small, Medium PP Colored Maxee Small, Medium& Large PC Clear Maxee Small & Large PP Opaque Lip Ring Small & Large PE Lip Ring Small & Large PE Scandee Extendo PP

Anterior Posterior Clear PC  
Combee Small,& Large Clear PC  
L-C PP Medium Opaque PP  
L-C PP Medium Clear PP  
Single sided Large Clear PC  
Single sided Small Clear PC  
Occlusal Long Clear PC  
Occlusal Short Clear PC  
TCL Small clear PC  
TCL Small Colored PP  
TCL Large Clear PC  
TCL Large Colored PP  
K&K Small Clear Short Handle PC  
K&K Medium Clear Short Handle PC  
K&K 45°Small Clear Long Handle PC  
K&K 45°Medium Long Handle PC  
LC Adult Clear PC  
LC Teen Clear PC  
LC Pedo Clear PC  
Occlusal 45° Fork Small Clear PC  
Occlusal 45° Fork Small Opaque PP  
Occlusal 45° Fork Large Clear PP  
Occlusal 45° Fork Large Opaque PP

**Material:**

PC - Polycarbonate Clear or colored  
PP - Polypropylene Opaque or colored

We, Saga Dental Supply AS, 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 referred herein are marked with CE marking according to the specified directive with applied strands 980:2008 symbols & ISO 15223-1 :2012 symbols,

*ISO 13485:2016, & ISO 15223-1:2016 symbols, Risk management ISO 14971:2012.*

**Where indicated and applied**

This document expires on 01.01.2023

Signed this on the behalf of Saga Dental Supply AS by

*Swadesh Kumar*

Dr. Swadesh Kumar BDS, D. Orth  
MD

