



DECLARATION OF CONFORMITY

Applicable Council Directive..... 93/42/EEC (as amended by 2007/47/EC)

Conformity Assessment Procedures Annex V per Article 11-3(b)(ii)

Classification..... Class IIb per Annex IX, Rule 8

Product Name..... Orthodontic Anchoring Screw

GMDN Code 46536

Catalog Numbers SAMS12; Storm Mini Screw 1.5mm Head, 1.5mm Neck
SAMS14; Storm Mini Screw 2mm Head, 1.5mm Neck
SAMS15; Storm Mini Screw 2mm Head, 3mm Neck

Manufacturer Name and Address Lancer Orthodontics, Inc.
2726 Loker Avenue West
Carlsbad, California 92010
USA

European Representative Kristal S.r.l.
Via Claudio Cogorano 25
IT-57123 Livorno (LI)
Italy
Tel: +39 024453401
Fax: +39 0248408305
e-mail: info@kristalsrl.net

Notified Body BSI
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

This product is marked with the CE Marking and Notified Body Number (2797) according to the specified Council Directive.

Certificate Number CE 02013

Date of Expiry 15 July 2023

The undersigned hereby declares, on behalf of Lancer Orthodontics, Inc. of Carlsbad, California USA, that the above-referenced product, to which this declaration relates, is in conformity with the provisions of Council Directive 93/42/EEC (as amended).

Regulatory Affairs Manager

12 February, 2020

Date