DECLARATION OF CONFORMITY

Applicable Council Directive	93/42/EEC (as amended by M5)
Conformity Assessment Procedures	Annex VII per Article 11-5
Classification	Class I Transient per Definition 1.1, Rule 1
Product Name	Orthodontic Surgical Kit – Non-Sterile

Catalog Numbers & Descriptions

SASKIT	Surgical Kit
SASKIT-R1	Manual Screwdriver
SASKIT-R2	Connector Handpiece-20mm
SASKIT-R3	Connector Handpiece-25mm
SASKIT-R4	Bur Dia. 1.1mm/Length 7mm
SASKIT-R5	Bur Dia. 1.4mm/Length 8mm
SASKIT-R6	Handle Driver

Manufacturer Name and Address
Lancer Orthodontics, Inc.
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Notified Body
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This product is marked with the CE Marking 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 Vista, 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

28 March, 2019
Date

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