



# DECLARATION OF CONFORMITY

Applicable Council Directive..... 93/42/EEC (as amended by M5)

Conformity Assessment Procedures ..... Annex V per Article 11-2(b)

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.  
2726 Loker Avenue West  
Carlsbad, California 92010  
USA

European Representative .....

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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) and carries the CE marking accordingly.

  
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 Regulatory Affairs Manager

12 February, 2020  
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 Date