DIRECTA

EU Declaration of Conformity

Manufacturer

DIRECTA AB
Finvids väg 8-10, SE-194 47 Upplands Väsby, Sweden

SRN

SE-MF-000002500

Basic UDI-DI

731023999528B8

Model/Product code/Trade and device name

Model	REF	Trade and device name
L1S	506355 506355U	Luxator® Periotome
L2S	506352 506352U	
L3C	506341 506341U	
L5S	506342 506342U	
L5C	506343 506343U	
L3S	506340 506340U	
L3CA	506353 506353U	
L3IC	506354 506354U	
LK4	506330 506330U	
LK7	506331 506331U	
LK VET	506332 506332U	
S2S	506358 506358U	Luxator® Short Periotome
S3C	506359 506359U	
S3S	506360 506360U	
S3CA	506361 506361U	
S5S	506362 506362U	
SK4	506333 506333U	
L3S TiN	506433 506433U	Luxator® Periotome TiN
L2S TiN	506434 506434U	
L3A TiN	506436 506436U	
DE3 TiN	506435 506435U	Luxator® Dual Edge Periotome TiN
DE3	506356 506356U	Luxator® Dual Edge Periotome
DE5	506357 506357U	

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Intended purpose	Instrument are used to luxate the tooth before final extraction. Intended users are dentists and dental surgeons. To be processed by dental personnel.
Risk Class	Class Ir, rule 6
Common specification (CS)	N/A
Notified body	Intertek Medical Notified Body AB, NB 2862
Conformity Assessment Procedure	Chapter I and III of Annex IX
Certificate ID	28620139228
Statement	This EU declaration of conformity is issued by under the sole responsibility of Directa AB. The device covered by this declaration is in conformity with Regulation (EU) 2017/745 on medical devices.

On behalf of Directa AB

Upplands Väsby, 2023-09-22

Henric Karsk
CEO

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