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
F25	506370 506370U	Luxator® Forte Elevator
F32	506371 506371U	
F32C	506373 506373U	
F40	506372 506372U	

Intended purpose	Instrument to be used for elevation of the tooth during 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, 2023-10-23

Henric Karsk
CEO

First version of EU Declaration of Conformity (MDR) issued year 2023.
TF12.1_DoC_EN_2023-10-23

DIRECTA AB
Finvids väg 8-10
P.O. Box 723
SE-194 27 Upplands Väsby Sweden

Tel +46 8 506 505 75
Fax +46 8 590 306 30
www.directadental.com
info@directadental.com

VAT-No SE556013882701
Organisationsnr 556013-8827
Bank SEB, KABV
SE-10640 Stockholm, Sweden

Swift Code ESSESESS
IBAN SE38 5000 0000 0538 5100 6232
Bank Account 5385-10 062 32
National 433-8810