

EU Declaration of Conformity

Manufacturer	DIRECTA AB Finvids väg 8 SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-ID	731023999507AY
Product and trade name	FenderWedge, FenderWedgePrep
Product code/REF	602745, 602749, 602750, 602751, 605752, 602753, 602754, 602755, 602800, 602801, 602802, 602803, 602811
Intended purpose	Interdental wedge to separate and shield to protect adjacent teeth. Intended user is professional licensed dentist.
Risk Class	Class I, rule 5
Common specification (CS)	N/A
Notified body	N/A
Conformity Assessment Procedure	Article 52, paragraph 7
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.

Upplands Väsby, 2021-05-18



Henric Karsk
CEO

*First version of EU Declaration of Conformity (MDR) issued year 2021.
TF19_DoC_EN_2021-05-18*