DIRECTA

EU Declaration of Conformity

Manufacturer	**DIRECTA AB** Finvids väg 8 SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-ID	731023999506AW
Product and trade name	**FenderMate, FenderMate D-Coat, FenderMate Prime, FenderMate Temp**
Product code/REF	602770, 602771, 602772, 602773, 602774, 602804, 602805, 602806, 602807, 602775, 602815, 602816, 602817, 602808, 602809, 602812, 602786, 602813, 602768, 602990, 602991, 602992, 602993, 602994, 602679
Intended purpose	Sectional matrix made of plastic wedge and steel plate. 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

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