

EU/UK Declaration of Conformity

Manufacturer	DIRECTA AB Finvids väg 8, SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-DI	731023999514AV
Product and trade name	ContacEZ Strips
Product code/REF	As per REF listed in TF38_List of item numbers
Intended purpose	Remove and/or finish dental enamel or filling materials. Intended user is professional licensed dentist.
Risk Class	Class I, rule 5
Common specification (CS)	N/A
Notified body	N/A
Conformity Assessment Procedure	(EU) Article 52, paragraph 7
Statement	This EU and UK 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 and UK MDR 2002 on medical devices.

Upplands Väsby, 2021-11-19



Henric Karsk
CEO

*First version of EU Declaration of Conformity (MDR) issued year 2021.
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