

EU Declaration of Conformity

Manufacturer	DIRECTA AB Finvids väg 8, SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-ID	731023999510AM
Product and trade name	SpotIt
Product code/REF	690110, 690111, 690112
Intended purpose	Articulating paper. 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.
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