

EU Declaration of Conformity

Manufacturer	DIRECTA AB Finvids väg 8 SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-ID	731023999509B4
Product and trade name	Cheek Retractor
Product code/REF	511582, 511583, 11584, 511585, 511586, 511587, 511588, 511589, 511590, 511591
Intended purpose	To keep the soft tissue away from teeth and to give improved access to working area in oral cavity. 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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