

EU Declaration of Conformity

Manufacturer	DIRECTA AB Finvids väg 8 SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-ID	731023999551AR
Product and trade name	TrollBag, Camera Sleeve, Camera Sheats, Sensor Sheats
Product code/REF	413190305, 413190306, 10008601, 13190091, 13200306, 13200300, 13200020
Intended purpose	Disposable barriers to reduce contamination of multi-used devices. 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, 2023-01-20



Henric Karsk
CEO

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