DIRECTA

EU Declaration of Conformity

Manufacturer	**DIRECTA AB** Finvids väg 8, SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-DI	731023999508B2
Product and trade name	**Stik-N-Place**
Product code/REF	539483
Intended purpose	The device is used as an aid to hold and apply small restorative objects in the oral cavity. Intended users: licensed dentists.
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, 2022-06-28

Henric Karsk
CEO

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