DIRECTA

EU Declaration of Conformity - ProphyCare®

Manufacturer	**DIRECTA AB** Finvids väg 8, SE-194 47 Upplands Väsby, Sweden
SRN	SE-MF-000002500
Basic UDI-ID	731023999500AJ
Product/trade name ProphyCare®	**Product code/REF** 731111, 731112, 731113, 731114, 741111, 690119, 690120, 690121, 690122, 690123, 690125 731115, 731116, 731118, 731119
Intended purpose	Tooth cleaning and polishing during prophylaxis treatments. To be used with polishing brush or cup. Intended users: Professional licensed dentist and dental hygienists
Risk Class	Class I, rule 5
Common specification (CS)	N/A
Notified body	N/A
Conformity Assessment Procedure	Article 52, paragraph 7 Annex II and III
Statement	We, Directa AB, confirm that this EU declaration of conformity is issued under our sole responsibility and that the device covered by this declaration is in conformity with Regulation (EU) 2017/745 on medical devices.

Upplands Väsby, 2024-03-22

Henric Karsk
CEO

First version of EU Declaration of Conformity (MDR) issued year 2022.
TF26_DoC_EN_2024-03-22