

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 [®] ProphyCare [®] Paraben Free	Product code/REF 731111, 731112, 731113, 731114, 741111, 690119, 690120, 690121, 690122, 690123, 690125 731115, 731116
Prophycare Paraben Free	/31113, /31110
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, 2022-09-12

Henric Karsk CEO

First version of EU Declaration of Conformity (MDR) issued year 2022. TF26_DoC_EN_2022-09-12

DIRECTA AB Finvids väg 8 P.O. Box 723 SE-194 27 Upplands Väsby Sweden Tel +46 8 506 505 75 Fax +46 8 590 306 30 www.directadental.com info@directadental.com VAT-No SE556013882701 Organisationsnr 556013-8827 Bank SEB, KABV SE-10640 Stockholm, Sweden Swift Code ESSESESS IBAN SE38 5000 0000 0538 5100 6232 Bank Account 5385-10 062 32 National 433-8810