

## EU Declaration of Conformity

**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**

Model	REF	Trade and device name
ProphyCare Yellow	731111	ProphyCare®
ProphyCare Red	731112	
ProphyCare Blue	731113	
ProphyCare Green	731114	
ProphyCare PRO	741111	
ProphyCare Yellow Single Dose	690120	
ProphyCare Red Single Dose	690121	
ProphyCare Green Single Dose	690122	
ProphyCare Blue Single Dose	690123	
ProphyCare PRO Single Dose	690125	
ProphyCare Red, Paraben free	731115	
ProphyCare Blue, Paraben free	731116	
ProphyCare Yellow, Paraben free	731118	
ProphyCare Green, Paraben free	731119	
ProphyCare HAp	731117	

**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

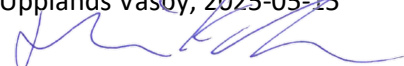
**Common specification (CS)** N/A

**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, 2025-05-15



Henric Karsk  
CEO

*First version of EU Declaration of Conformity (MDR) issued year 2022.  
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