

EU DECLARATION OF CONFORMITY

We, SmartHealth, Inc. (dba SmartPractice) of 3400 East McDowell Road, Phoenix, Arizona, USA declare under our sole responsibility that the following Class I Finn Chambers Products for epicutaneous diagnostic patch testing described below are in conformity with the applicable provisions of Medical Devices Regulation (EU) 2017/745 concerning the medical devices and its Annex IV and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Product Category	Proprietary/ Trade Name	Configuration	GMN/Basic UDI-DI	GTIN/UDI-DI
Medical Device	Finn Chambers® on Scanpor®	25 strips of 10 patch chambers (five 8 mm chambers/2 rows)	0854498007AL7000WL	00854498007191
		100 strips of 10 patch chambers (five 8 mm chambers/2 rows)		00854498007153
		50 strips of 5 patch chambers (five 8 mm chambers/1 row)		00854498007177
		200 strips of 5 patch chambers (five 8 mm chambers/1 row)		00854498007214
		200 panels of one 12 mm (Large) patch chamber		00854498007344
		ATOPY 50 strips of 5 patch chambers (five 12 mm chambers/1 row)		00854498007481
	Finn Chambers® on Scanpor® PP Coated	100 strips of 10 patch chambers (five 8 mm chambers/2 rows)	0854498007AL7001WN	00854498007160
		150 panels of one 8mm patch chamber		00854498007221
		200 panels of one 12 mm (Large) patch chamber		00854498007351
		100 panels of one 18 mm (Extra Large) patch chamber		00854498007337
	Finn Chambers®, Loose Chamber PP Coated	100 chambers par pack, 18 mm (Extra Large, PP coated)	0854498007AL7120WX	00854498007269

Note: Our Authorized Representation within the EU is Dr. Ebeling & Assoc. GmbH Isestrasse 5 · 20144 Hamburg Germany, SRN: DE-AR-000000003

Product Category	Proprietary/ Trade Name	Configuration	GMN/Basic UDI-DI	GTIN/UDI-DI
	Finn Chambers® on Scanpor® OPEN	50x10 (5 chambers/2 rows), 8 mm	0854498007AL7005WW	00854498007146
	Finn Chambers® AQUA	100 strips of 10 patch chambers (five 8 mm chambers/2 rows)	0854498007AL7006WY	00854498007450
	Finn Chambers®, Loose Chambers	1000 chambers per pack, 8 mm	0854498007AL7100WR	00854498007368
		200 chambers per pack, 12 mm (Large)		00854498007245
	Accessory	Finn Chambers® Filter Paper Discs	1000 discs per pack; 8 mm	0854498007AL7200WW
200 discs per pack; 8 mm			00854498007405	
200 discs per pack, 12 mm (Large)			00854498007375	
100 discs per pack, 18 mm (Extra Large)			00854498007382	
patchProtect®		25 per pack, small (155 x 80 mm)	0854498007AL1701WF	00854498007474
		100 per pack, small (155 x 80 mm)		00854634003032
		100 per pack, medium (155 x 140 mm)		00854498007054
		100 per pack, large (155 x 200 mm)		00854634003056
		Assorted: 75 per pack, 25 of each size (small / medium / large)		00854634003025
TruVol®		20 dispensers per pack (one size)	0854498007AL7950YG	00854634003049

Phoenix, Arizona



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