

Declaration of Conformity

Manufacturer	J H Orsing AB Torbornavägen 26 SE-253 68 Helsingborg, Sweden	
SRN	SE-MF-000003934	
Basic UDI-DI	739350799901KZ	
Product name		REF
	Hygovac	V100
	Hygovac Bio	B100, B100LG
	Hygovac Short Bio	BS100, BS100LG
	Hygovac Vent	V100V
	Hygovac Vent Bio	VB100V
	Hygovac Blue	V100B
	Scantube	AT100, BK100, BL100, LB100, LC100, LG100, MG100, OR100, PK100, PU100, YW100
	Scantube Bio	AB100
	Scantube Vent	AV100, AV100BL, AV100LB, AV100MG, AV100OR, AV100PU,
	Scantube Vent Bio	AVB100
	Spotnix	SPB100, SPB1000
	Angles	A100
	Hygotip	TP25
	Hygotip XL	TPXLB10
	Hygoyet	HJ25
Intended purpose	Disposable aspirator tubes used in oral cavity during dental procedures. Aspirator tubes are intended to remove fluid (water, saliva and blood) and debris from the patient's mouth during dental procedures, with the purpose to achieve a dry clean working field.	
Risk Class	Class IIa, rule 5	
Common specifications (CS)	N/A	
Notified body	Intertek Medical Notified Body AB, NB 2862	
Conformity assessment procedure	Annex XI	
Certificate ID	28620149273	
Statement	This EU declaration of conformity is issued by under the sole responsibility of J.H. Orsing AB. The device covered by this declaration is in conformity with Regulation (EU) 2017/745 on medical devices.	

Visiting address
Torbornavägen 26
Ättekulla industriområde
HELSINGBORG
www.orsing.se
Org.No/VAT No SE 55609963201

Postal address
P.O. Box 16077
S-250 16 RÅÅ
SWEDEN

Telephone:
+46-42-295500
Telefax:
+46-42-295505
Email:
orsing@orsing.se

Bankers
Swedbank
S-105 34 Stockholm,
SWEDEN
Swift: SWEDSESS

Banking account
653-0091
Account no 8214-9
6741512922 (SEK)
037670679-2 (EUR)

Iban
SEK-account
SE6580000821496741512922
EURO-account
SE7680000821490376706792

On behalf of JH Orsing AB

Helsingborg, 2023-10-27



Nenad Trlin
CEO

TF11_DoC_EN_rev.07

Visiting address

Torbomavägen 26
Ättekulla industriområde
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Bankers

Swedbank
S-105 34 Stockholm,
SWEDEN
Swift: SWEDSESS

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