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TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

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Your reference/letter of	Our reference/name	Tel. extension/Email	Mobile	Date	Page
	PS-MHS-RM-17/ Max Huhn	+49 89 50084-840 Max.Huhn@tuvsud.com	+4915111540712	2024-05-24	1 of 3

TÜV SÜD Product Service GmbH
Receipt of formal application

Reference: 713318557

To whom it may concern,

Confirmation of the status of a formal application in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received **a formal application** in accordance with Section 4.3, first subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: DE-MF-000007090

The devices covered by the formal application mentioned above are identified in the Table below.

Please note that this letter only confirms the status of the formal application.

To benefit from the additional transitional provisions in the framework of Regulation EU 2023/607, TÜV SÜD Product Service GmbH and the manufacturer need to sign a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR latest until 26 September 2024.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
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VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

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Board of Management:
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TÜV®



In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-05-24


Max Huhn (24. Mai 2024 08:43 GMT+2)

Max Huhn
Customer Relationship Manager
PS-MHS-RM-17

Devices covered by the formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR

Device Name	Article Number	Basic UDI-DI
Vyntus ONE DL DLCO RT SB/IB	V-178601	42508929041512AHT
Vyntus ONE PFT N2 wash-out, DLCO RT SB/IB	V-178602	42508929041512AHT
Vyntus ONE N2 washout, DLCO RT SB/IB, BxB	V-178603	42508929041512AHT
SentrySuite 3.20	V-770965	42508929051912AK4
SentrySuite 3.30	V-770968	42508929012112AG30
Vyntus BODY SeS for FRCpl and Raw	V-178500	42508929031412AH7
Vyntus Pneumo EU; PC-Spirometer	V-171493	42508929041142AHE
Vyntus IOS EU; Impulse Oscillo	V-176435	42508929041122AH4
Vyntus APS/PNEUMO EU; Provocation Spiro	V-146406	42508929041112AGX
Vyntus APS/IOS EU; Provocation incl. IOS	V-146407	42508929041112AGX
Vyntus SPIRO (SeS) VC, FV-loop and MVV	V-171461	42508929041132AH9
Vyntus Spiro TP Spirometer with SeS	V-171466	42508929041132AH9
Vyntus ECG PC for Resting ECG AHA	V-178100	42508929051212AHK
Vyntus WALK 6MWT Tablet w. APP w. SpO2	V-178501	42508929111312AGP
Vyntus CPX PC Table Version	V-178001	42508929031812AJ3
Vyntus CPX PC with CART 3.0	V-178003	42508929031812AJ3
Vyntus CPX incl. Vyntus ECG	V-178021	42508929031812AJ3
Vyntus CPX PC with CART 3.0 & Vyn ECG	V-178023	42508929031812AJ3
Vyntus CPX PC with CART 3.0 GE Config.	V-178030	42508929031812AJ3
Vyntus CPX CART 3.0 w. ECG/suction unit	V-178031	42508929031812AJ3
Vyntus CPX PC Canopy with CART Version 3.0	V-178035	42508929031812AJ3
Vyntus CPX PC Canopy Table Version	V-178036	42508929031812AJ3
MicroGard IIB 50 pcs 50 pcs/pack	V-892381	42508929220112AGU
MicroGard IIC 50 pcs 50 pcs/pack	V-892384	42508929220112AGU
Mouthpiece Silicone Children Pack of 5	V-892230	42508929022012AG9



Mouthpiece Silicone Adult Pack of 5	V-892235	42508929022012AG9
Mouthpiece disposable ID 30 soft	V-892893	42508929151112AHV
Mouthpiece disposable ID 30 soft, 180 ea	V-892894	42508929151112AHV
Mouthpiece plastic disposable 25ea/pk	892103	42508929051412AHZ
Filter Kit MicroGard Type IIB	V-892391	42508929220112AGU
Filter Kit MicroGard Type IIC	V-892392	42508929220112AGU
MicroGard IIB	V-892386	42508929220112AGU
MicroGard II Sample Pack	V-892388	42508929220112AGU
Vyntus CPX Option High / Low FIO2	V-375650	42508929031812AJ3
Vyntus CPX Canopy Option (REE)	V-375660	42508929031812AJ3
Vyntus CPX Mixing Chamber Option	V-375675	42508929031812AJ3
Vyntus BODY TP Version for Vyntus ONE	V-378540	42508929031412AH7
Compliance Option for Vyntus ONE/BODY	V-578605	42508929031412AH7
Diffusion SB RT Option for Vyntus BODY	V-378501	42508929031412AH7
Diffusion SB RT subsequently Vyntus BODY	V-378502	42508929031412AH7
Height adjustable CART 3.1N f. Vyntus BODY	V-378570	42508929031412AH7
SNIP Option for Vyntus ONE/BODY	V-578603	42508929031412AH7
Rhinomanometry Option for Vyntus ONE/BODY	V-578604	42508929031412AH7
Compliance Option for Vyntus ONE/BODY	V-578603	42508929041512AHT
Rhinomanometry Option for Vyntus ONE/BODY	V-578604	42508929041512AHT
Compliance Option for Vyntus ONE/BODY	V-578605	42508929041512AHT
Vyntus APS Provo Module for Vyntus BODY	V-378510	42508929041112AGX
APS Provo Option for Vyntus PNEUMO/IOS	V-375171	42508929041112AGX
APS Provo Opt. For MSC Body	V-375172	42508929041112AGX
IOS Opt. For Vyntus PNEUMO/APS	V-376402	42508929041122AH4
Vyntus Spiro PTA	V-707293	42508929041132AH9
Repl. Kit Vyntus SPIRO PT Handle	V-707254	42508929041132AH9
VYN SPIRO LOW COST NB DE	V-707357	42508929041132AH9
Option Vyntus ECG for Vyn CPX AHA	V-375610	42508929051212AHK
Vyntus ECG with IEC labeling Vyntus ECG	V-375611	42508929051212AHK
Vyntus ECG exchange to connector	V-375690	42508929051212AHK
Vyntus ECG Option for Resting ECG AHA	V-375695	42508929051212AHK
Vyntus ECG Kit AHA	V-707277	42508929051212AHK
Vyntus ECG conn Kit	V-707356	42508929051212AHK
Vyntus ECG Kit IEC	V-707745	42508929051212AHK