nova:med GmbH, Schwarzenbacher Ring 5, 91315 Höchstadt

Name und Anschrift / Name and address

Ort, Datum / Place, date

nova:med GmbH

Schwarzenbacher Ring 5
91315 Höchstadt

T: 09193 507 106-0
F: 09193 507 106-50
info@novamed.de
www.novamed.de

Zolldeklaration / customs declaration

Sehr geehrte Patientin, sehr geehrter Patient,

gerne senden wir Ihnen für Ihre anstehenden Reisen nachstehende Erklärung für Ihr Therapiesystem:

Therapiegerät: Servoventilationsgerät AirCurve 10 CS PaceWave
Seriennummer:

Zollbescheinigung für Ihr Therapiesystem/
Customs declaration for your therapy device

Hiermit wird bestätigt, dass oben genanntes Gerät ein medizinisch therapeutisches Gerät ist. Es dient zur Behandlung von respiratorischen Erkrankungen und sollte vom Patienten regelmäßig angewendet werden. Der Patient muss daher das Gerät inklusive dem dazugehörigen Zubehör auf Reisen unbedingt mit sich führen und anwenden.

It is hereby confirmed that the above device is a medical device. It is used to treat respiratory diseases and should be used regularly by the patient. Therefore, the patient must always carry it with him including the necessary accessories while travelling.

Bei Rückfragen stehen wir Ihnen gerne zur Verfügung.

Ihre

nova:med GmbH

Adresse
nova:med GmbH
Schwarzenbacher Ring 5
91315 Höchstadt
IK-Nr. 330 906 334

Kontakt
T: 09193 507 106-0
F: 09193 507 106-50
info@novamed.de
www.novamed.de

Geschäftsführer
Frank Rebbert
USt-IDNr. DE815641534
AG Fürth HRB 23042
St.-Nr. 216/170/50002

Bankverbindung
VR Bank Metropolregion Nürnberg eG
IBAN DE93 7606 9559 0000 9428 20
UNICREDIT Bank GmbH
IBAN DE16 7602 0070 0049 3306 77

ResMed

September 22, 2022

Travel Compliance Letter for ResMed Therapy Devices

To whom it may concern,

ResMed respiratory assistive devices (ventilators, respirators, and CPAP machines) are medical devices prescribed for use on or by the order of a physician and are cleared for sale by the U.S. Food and Drug Administration, a branch of the Federal Government of the United States of America, and the Australian Therapeutics Goods Administration.

The devices do not contain any parts or materials known to cause or interfere with the safe operation of a commercial aircraft.

The U.S. Department of Transportation (DOT) Final Rule, “Non-discrimination on the Basis of Disability in Air Travel” (73 FR 27614 which updates Title 14 CFR Part 382), effective May 13, 2009, provides important new requirements for the accommodation of passengers with respiratory assistive devices.

Specifically, respiratory assistive devices may be used on board an aircraft, without further testing by the carrier, provided they have been tested for electromagnetic compatibility (EMC) in accordance with the current version of RTCA/DO-160, Section 21, Category M.

ResMed has successfully completed testing for the respiratory assistive devices described in this letter. **The devices listed below comply with RTCA/DO-160G, Section 21, Category M, and are considered FAA compliant.** *This information may be engraved on the device or a sticker label applied to the device; either method for identifying FAA compliance is acceptable and in accordance with DOT regulations.*

ResMed product	Product codes
AirCurve™ 10 ASV	37042, 37043, 37044, 37092, 37215, 37216, 37229, 37230, 37291, 37410, 37411, 37384, 37144
AirCurve 10 CS PaceWave™	37060, 37061, 37062, 37069, 37070, 37114, 37275, 37276, 37277, 37278, 37279, 37280, 37281, 37282, 37283, 37284, 37341, 37354, 37369, 37438, 37459, 28517, 28516
Aircurve 10 CS-A	28281
Aircurve 10 CS-A PaceWave™	28282,28283, 28284
Aircurve 10 CS-A TJ	28280
AirCurve 10 S	37045, 37046, 37047, 37048, 37068, 37093, 37213, 37214, 37227, 37228, 37250, 37251, 37290, 37340, 37351, 37397, 37408, 37409, 37116, 37107
AirCurve 10 ST	37056, 37057, 37058, 37073, 37095, 37306, 37307, 37348, 37349, 37373, 37374, 37375, 37412, 37413, 37385, 37145, 37111
AirCurve 10 ST-A	28210, 28211, 28219, 28323, 28326, 28285, 28340
AirCurve 10 VAuto	37050, 37051, 37052, 37053, 37054, 37055, 37059, 37094, 37109, 37211, 37212, 37225, 37226, 37238, 37239, 37248, 37249, 37261, 37262, 37267, 37272, 37289, 37391, 37392, 37406, 37407, 37450, 37481, 37383, 37143, 37110, 37108
AirMini™ AutoSet	38112, 38113, 38119, 38121, 38122, 38139, 38140, 38145, 38151
AirSense™ 10 AutoSet™	37027, 37028, 37029, 37030, 37031, 37032, 37033, 37064, 37065, 37067, 37090, 37101, 37102, 37207, 37208, 37221, 37222, 37236, 37237, 37245,

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nova:med GmbH
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ResMed product	Product codes
	37246, 37254, 37258, 37259, 37266, 37271, 37273, 37274, 37287, 37294, 37315, 37316, 37319, 37321, 37327, 37339, 37352, 37367, 37372, 37402, 37403, 37415, 37436, 37445, 37448, 37453, 37457, 37382, 37142, 37497, 37496, 37122, 37503, 37146, 37147, 37504, 37505, 37147, 37494, 37103, 37106
AirSense 11 AutoSet	39000, 39001, 39007, 39140, 39141, 39163, 39180, 39181, 39190, 39191, 39420
AirSense 10 AutoSet for Her	37034, 37035, 37036, 37037, 37039, 37040, 37041, 37066, 37091, 37104, 37105, 37209, 37210, 37223, 37224, 37247, 37260, 37288, 37295, 37317, 37318, 37320, 37322, 37328, 37353, 37368, 37390, 37396, 37404, 37405, 37420, 37421, 37422, 37423, 37430, 37434, 37437, 37446, 37449, 37454, 37458
AirSense 10 CPAP	37014, 37015, 37016, 37017, 37018, 37063, 37072, 37088, 37203, 37204, 37217, 37218, 37285, 37311, 37312, 37325, 37395, 37398, 37399, 37440, 37461, 37497
AirSense 11 CPAP	39002, 39003
AirSense 10 Elite	37019, 37020, 37021, 37022, 37023, 37024, 37025, 37043, 37071, 37089, 37118, 37205, 37206, 37219, 37220, 37234, 37235, 37243, 37244, 37256, 37265, 37270, 37286, 37313, 37314, 37326, 37338, 37355, 37366, 37371, 37393, 37400, 37401, 37424, 37425, 37439, 37444, 37455, 37460, 37495, 37424, 37117, 37100
AirSense 11 Elite	39004, 39005, 39142, 39143, 39162, 39179
AirSense 10 Respond A	37416
AirSense 10 Respond W	37417
AirStart™ 10 APAP	37008, 37009, 37202, 37241, 37365
AirStart 10 CPAP	37002, 37004, 37201, 37240, 37364, 37370
Astral™ 100	27001, 27011, 27012, 27021, 27031, 27032, 27051, 27052, 27061, 27062, 27071, 27072, 27081, 27082, 27091
Astral 150	27003, 27013, 27014, 27023, 27033, 27039, 27053, 27054, 27063, 27064, 27068, 27073, 27074, 27083, 27084, 27088, 27093, 27094
Astral External Battery	27918, 27919
Climate Control kit	36875, 36876, 36905, 36915, 36917
LifeChoice Activox™ POC	XYC100, XYC100A, XYC100RA, XYC100RB, XYC102R, XYC100B, XYC100B-PRO, XYC100B-SPT, XYC100B-P4L, 200122
Lumis 100 VPAP S	28001, 28002, 28003, 28004, 28005, 28006, 28007, 28008, 28009, 28010, 28011, 28012, 28013, 28302, 28303, 28304, 28322, 28502
Lumis 100 VPAP ST	28101, 28102, 28103, 28104, 28105, 28106, 28107, 28108, 28109, 28306, 38305, 38307, 28505
Lumis 100 VPAP ST-A	28201, 28221, 28313, 28332, 28513
Lumis 150 VPAP ST	28110, 28111, 28112, 28113, 28114, 28115, 28116, 28117, 28118, 28119, 28120, 28121, 28122, 28123, 28124, 28125, 28308, 28309, 28310, 28311, 28312, 28506, 28507, 28508, 28509

ResMed Corp 9001 Spectrum Center Blvd. San Diego, CA 92123 USA ▪ **T** 1 800 424 0737 ▪ **F** 1 858 836 5000
ResMed Pty Ltd 1 Elizabeth Macarthur Drive Bella Vista NSW 2153 Australia ▪ **T** +61 (2) 8884 1000 ▪ **F** +61 (2) 8884 2000
ResMed (UK) Ltd 8 Wimpole Street, London W1G 9SP, UK ▪ **T** +44 (1235) 862 997 ▪ **F** +44 (1235) 831 336
ResMed.com

109120/19 2018-6

Adresse
nova:med GmbH
Schwarzenbacher Ring 5
91315 Höchstadt
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ResMed product	Product codes
Lumis 150 VPAP ST-A	28202, 28203, 28204, 28205, 28206, 28207, 28208, 28216, 28220, 28222, 28223, 28226, 28315, 28316, 28317, 28318, 28320, 28333, 28314, 28511, 28512, 28515, 28514
Lumis HFT	28401
Mobi	35001, 35003, 35004, 35005, 35006, 35009, 35013
POC External Battery	35052
ResMed Power Station II (RPS II)	24921, 24923, 24925, 24926, 24946, 24947, 24959, 24960, 24961, 24962, 24963, 24964, 24981, 24990, 36821, 36822, 36823, 36824, 37342, 37343
S8™ Auto 25	26104, 26105, 26125, 26126
S8 AutoScore II	33044
S8 AutoSet	33105, 33138
S8 AutoSet II	33129, 33141, 33150
S8 AutoSet Spirit	19423, 19426, 33113, 33121, 33122, 33123, 33124, 33125, 33126
S8 AutoSet Spirit II	33130, 33131, 33132, 33133, 33134, 33135, 33136, 33143, 33144, 33145, 33146, 33147, 33148
S8 AutoSet Vantage	19420, 33112
S8 Elite	19413, 19414, 33021, 33026, 33027, 33028, 33031
S8 Compact	19404, 33030
S8 Elite II	33039, 33040, 33041, 33042, 33043, 33045, 33062, 33072, 33073, 33074, 33075
S8 Escape™	19405, 19408, 19409, 19410, 33001, 33002, 33003, 33007, 33009, 33013, 33024, 33036, 33060
S8 Escape II	33048, 33051, 33052, 33053, 33054, 33061, 33064
S8 Lightweight	33032
S8 Lightweight II	33055
S8 Respond	33128, 33137
S9™ AutoSet	36005, 36015, 36025, 36084, 36085, 36086, 36087, 36088, 36089, 36095, 36105, 36115, 36125, 36145, 36180, 36185, 36205, 36225, 36245, 36265, 36285, 36305, 36325, 36345, 36365, 36375, 36385
S9 AutoSet 25	36106, 36116, 36126, 36146, 36206, 36226, 36266, 36296, 36366
S9 AutoSet CS	36100, 36110, 36120, 36140, 36200, 36220, 36240, 36260, 36360
S9 AutoSet CS PaceWave	36160, 36170
S9 AutoSet CS-A	36211, 36351, 36390
S9 AutoSet for Her	36015, 36065, 36075
S9 Elite	36003, 36013, 36023, 36083, 36093, 36103, 36113, 36123, 36143, 36183, 36203, 36223, 36243, 36263, 36303, 36343, 36363, 36373
S9 Escape	36001, 36011, 36021, 36081, 36091, 36121, 36141, 36201, 36221, 36261, 36301, 36361
S9 Escape Auto	36002, 36012, 36022, 36092, 36122, 36302, 36362

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nova:med GmbH
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ResMed product	Product codes
S9 VPAP™ Adapt	36007, 36017, 36027, 36037, 36047, 36057, 36097, 36367, 36377
S9 VPAP Adapt SV	26008, 26009, 26011, 26013, 26928
S9 VPAP Adapt SV-A	36331
S9 VPAP Auto	36006, 36016, 36026, 36096
S9 VPAP S	36004, 36014, 36024, 36094, 36114, 36124, 36144, 36204, 36224, 36244, 36264, 36284, 36304
S9 VPAP ST	36008, 36018, 36028, 36098, 36108, 36118, 36128, 36148, 36208, 36228, 36248, 36368, 36378
S9 VPAP ST-A	36009, 36039, 36049, 36059, 36099, 36119, 36129, 36159, 36169, 36209, 36219, 36239, 36339, 36359, 36379
Sleepmate 10 Auto	37418
Sleepmate 10 Elite	37419
Stellar™ 100	24151, 24152, 24153, 24154, 24155, 24156, 24157, 24158, 24159, 24163, 24164, 24166, 24168, 24170
Stellar 130	24172
Stellar 150	24140, 24141, 24142, 24143, 24144, 24145, 24146, 24147, 24149, 24160, 24161, 24162, 24165, 24167, 24169
VPAP IV	26102, 26103, 26106, 26107, 26108, 26109, 26123, 26127
VPAP IV ST	26112, 26113, 26114, 26115, 26116, 26117, 26118, 26124
VPAP Auto 25	26101, 26111, 26121
VPAP S	26119, 26120
VPAP ST	26110, 26122

Not all products are available in each country/region. Please check with your regional representative for specific country availability.

Please contact ResMed Customer Service with any questions.

Australia:	+61 (2) 8884 1000, 1800 658 189 (Toll free)
New Zealand:	+0800 737 633 (Toll free)
United Kingdom:	+44 (1235) 862 997
EU, France:	+33 (0) 1 60 183 600
United States:	+1 (800) 424 0737 (Toll free)

Kind regards,

Sheila Bruschi
Director, Regulatory Affairs
Sheila.bruschi@resmed.com

Adresse
nova:med GmbH
Schwarzenbacher Ring 5
91315 Höchstadt
IK-Nr. 330 906 334

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