Ventilator Equipment Order Form

This Order Form is issued by the Authority subject to (i) the Terms and Conditions for the Supply of Ventilators in a National Emergency as supplied by the Authority and (ii) the Deed of Indemnity Regarding the Production of Ventilators in a National Emergency between the Authority and Supplier, among others, dated 13 April 2020 (the ***Deed***). No other terms or conditions shall apply to the order which is the subject of this Order Form.

The Supplier agrees to supply the Goods specified below on, and subject to, the terms of this Contract and for the avoidance of doubt the Contract consists of the terms set out in (i) this Order Form; (ii) the Terms and Conditions for the Supply of Ventilators in a National Emergency as supplied by the Authority; and (iii) the Deed.

Date of Order	29 May 2020	**Order no.**	29

From:

Authority name	THE MINISTER FOR THE CABINET OFFICE acting as part of the Crown
Authority's address	1 Horse Guards Road, London, SW1A 2H
Invoice Address *(if different)*	NEWPORT SSCL - CABINET OFFICE PO Box 405 NEWPORT NP10 8F
Address for notices to be given under the Contract *(if different)*	N/A
Authority Contract Manager	[redacted]

To:

Supplier name	Smiths Medical International Limited
Supplier's Address	1500 Eureka Park, Ashford, Kent TN25 4BF
Address for notices to be given under the Contract *(if different)*	**EMEA General Counsel, Legal Dept** Smiths Medical International Limited 1500 Eureka Park, Ashford, Kent, TN25 4BF (email: [redacted]) With a copy to: • General Counsel, Smiths Medical, 6000 Nathan Lane North, Plymouth, Minneapolis, MN 55442, USA (email: [redacted]) • Group General Counsel, Smiths Group Plc, 4th Floor, 11-12 St James' Square, London, SW1Y 4LB, UK (email: [redacted])

Supplier Contract Manager	[redacted]

Details of requirements:

Contract Term	The Contract shall expire on 30 June 2021, or such other date as the Authority and the Supplier may agree in writing from time to time.
Commencement Date *(if not the date of this Order Form)*	n/a
Goods purchased *(including description and quantity)*	Four thousand, four hundred and eighteen (4,418) units of ParaPac plus Model 300 Ventilators. Notwithstanding any other provisions of this Contract, no units will be accepted for delivery by the Authority under this Contract where such units have not been fully manufactured and dispatched by 30th June 2020.
Specification of Goods *(including applicable standards)*	Specification has the same meaning as that set out in the Deed
Deliverables	Full instruction manual provided at Appendix 1
Contract Price *(specify price and basis of calculation including the unit of purchase and unit price where applicable)*	See Clause 15 and Schedule 6 of the Terms and Conditions.
Delivery Site(s) *(where the Goods are to be delivered)*	[redacted]
Delivery date(s) / delivery instructions	Notwithstanding Table 1 below and the Terms, the Supplier shall notify the Authority in advance of the estimated date and time for delivery of the Goods. The Supplier is permitted to revise its delivery timelines on reasonable notice to the Authority, provided that no units will be accepted by the Authority under this Contract where such units have not been fully manufactured and dispatched by 30th June 2020. Subject to the foregoing, the Supplier shall use reasonable endeavours to deliver the Goods to the Authority according to the following estimated schedule: ***Table 1 Delivery timelines (indicative only)*** **Date (week ending)** | **Units**

	<table><tr><td>31 May 2020</td><td>38</td></tr><tr><td>7 June 2020</td><td>380</td></tr><tr><td>14 June 2020</td><td>900</td></tr><tr><td>21 June 2020</td><td>1,200</td></tr><tr><td>28 June 2020</td><td>1,400</td></tr><tr><td>to 30 June 2020</td><td>500</td></tr><tr><td>**Total Units**</td><td>**4,418**</td></tr></table> The Authority acknowledges and agrees that the delivery targets set in Table 1 above are non-binding indicative estimates only. The Supplier shall comply with delivery instructions as agreed between the Authority Contract Manager and Supplier Contract Manager from time-to-time.
Key Provisions *(add any additional Key Provisions to those set out in Schedule 1 of the Terms and Conditions, including any provisions on changes to regulatory requirements)*	The Supplier shall ensure that: (i) the Goods as supplied to the Authority shall be CE marked medical devices (subject to the acknowledgement and acceptance by the Authority of the MHRA agreement to the application of the CE mark to the Goods for the duration of and subject to MHRA's exceptional use authorisation detailed below) and, subject to (ii), shall in all other respects comply with Law and Guidance applicable to a CE marked medical device; (ii) any specific additional conditions of the MHRA in respect of the Goods which have been notified to the Supplier are complied with during the period that the Goods are manufactured subject to the MHRA's exceptional use authorisation; and (iii) the supply of the Goods is in line with agreed quality management systems adequate to ensure compliance with any regulatory requirements applicable to the Goods and their production, manufacture, assembly and testing. The Authority acknowledges and accepts that the MHRA has issued to the Supplier an exceptional use authorisation dated 27 May 2020, which together with the email conformation also dated 27 May 2020 (attached as Annex 1 to this Order Form), confirms that the Supplier is permitted to apply the CE mark to the Goods during the period of the exceptional use authorisation, subject to the terms and conditions set out in that correspondence.

Formation of Contract

The Supplier shall sign and return a copy of this Order Form to the Authority.
The Contract, governed by (i) the Terms and Conditions for the Supply of Ventilators in a National Emergency and (ii) the Deed, shall be formed when a copy of this Order Form which has been executed on behalf of the Supplier is executed on behalf of the Authority.

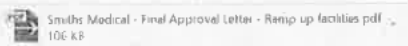
For and on behalf of the Supplier:

Signature	[redacted]
Name and Title	[redacted] Vice President & General Manager EMEA
Date	29 May 2020

For and on behalf of the Authority:

Signature	[redacted]
Name and Title	[redacted]
Date	28 May 2020

ANNEX 1


Smiths Medical - Final Approval Letter - Ramp up facilities.pdf
106 KB

From: [redacted]
Date: 27 May 2020 at 21:57:22 BST
To: [redacted]
Cc: [redacted]
Subject: EXTERNAL: RMVS -Smith's Medical Final Outcome (RMVS/27-05/01 - Smith's Medical)

CAUTION: This email come from outside Smiths Group. Be cautious with the contents unless you can confirm the sender is genuine.

Dear Mr [redacted]

Please see the outcome of your application through the RMVS Process attached.

As previously discussed the duration of this exceptional use authorisation is limited to a month to allow you to work with BSI to add these sites onto your CE Certificate. Please use this month to ensure all is in order as MHRA do not intend on extending this authorisation any further. I have included [redacted] in copy for BSI's records.

MHRA have taken a pragmatic approach which allows you to CE Mark products being released from the additional sites, however you are required to provide evidence of the devices from each location as stipulated within the letter.

Please do let me know if you require any further clarification.

Kind regards

[redacted]
Unit Manager – Notified Bodies, Market Surveillance & Clinical Evaluations
Medicines and Healthcare Products Regulatory Agency (MHRA)
Devices Regulatory Group
10 South Colonnade, Canary Wharf, London E14 4PU
Tel: +44 [redacted]
Email [redacted]

Medicines & Healthcare products
Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]
Director Global Audit Compliance
Smith's Medical
6000 Nathan Lane North, Minneapolis, MN 55442
USA

MHRA
10th Floor, Devices Division
10 South Colonnade
London
E14 4PU

www.gov.uk/mhra

27th May 2020

Our Ref: RMVS/27-05/01-Smith's Medical

Dear Mr [redacted]

REGULATION 12(5) OF MEDICAL DEVICES REGULATIONS 2002
AUTHORISATION TO SUPPLY RAPIDLY MANUFACTURED VENTILATOR SYSTEMS (RMVS) FOR FINAL USE

Following your application through the RMVS process to arrange for the manufacture and supply of ventilator systems (The Parapac Plus P300), in order to ensure the UK has an ongoing supply of those devices as a result of COVID-19.

After careful consideration of the outcome of the Quality Management System Gap and Microbiology assessments, the Secretary of State acting through the MHRA, has concluded that it is in the interests of the protection of health to authorise the supply of the non CE-marked RMVS Devices (listed in the Annex to this authorisation) under regulation 12 (5) of the Medical Device Regulations 2002 during the COVID-19 emergency, subject to the following conditions continuing to be met:

1. The authorisation commences on 27th May 2020 and, subject to paragraph 8, ends on whichever of the following days is sooner:

    a. the day 1 month after the authorisation commences; or

b. a day specified by the Secretary of State in writing as being the day on which the Secretary of State has determined that the need for the devices is over.

If this authorisation ends in accordance with paragraph 2a, it shall be reviewed by the MHRA and a decision taken on whether it remains in the interests of the protection of health for the devices to remain on the market or in service[1]. This authorisation has been added to the initial approval [Ref RMVS/27-05/01-Smith's Medical] dated 27th May 2020.

2. That you work with BSI to ensure the sites are added as critical subcontractors on your CE Certificate in a timely manner

3. That the MHRA receive confirmation of every batch released on the Market (including batch release site, batch numbers, numbers per batch and where each batch has been dispatched to). Confirmation must be sent to [redacted]@mhra.gov.uk & [redacted]@mhra.gov.uk.

4. That the healthcare institutions supplied with the devices in question are supplied with all necessary information and instructions for use.

5. That you put in place mechanisms for monitoring the performance of the devices.

6. That you agree to provide the MHRA with full details of **all** adverse incidents that occur in relation to the devices or result from the use of the device

7. That any changes you intend to make to the devices approved under this authorisation are reported to the MHRA, prior to implementation;

8. That the continuation of this derogation is dependent upon you continuing to meet the above-mentioned conditions.

[1] If this occurs a new authorisation will be issued.

Medicines & Healthcare products
Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Please take this letter as formal approval. Please contact me you require any clarification in relation to this process.

Yours sincerely

[redacted]

[redacted]
Clinical Director – Devices Clinical Team MHRA,
10th Floor, 10 South Colonnade, London, E14 4PU
E: [redacted]@mhra.gov.uk

Annex

List of devices covered by this authorisation

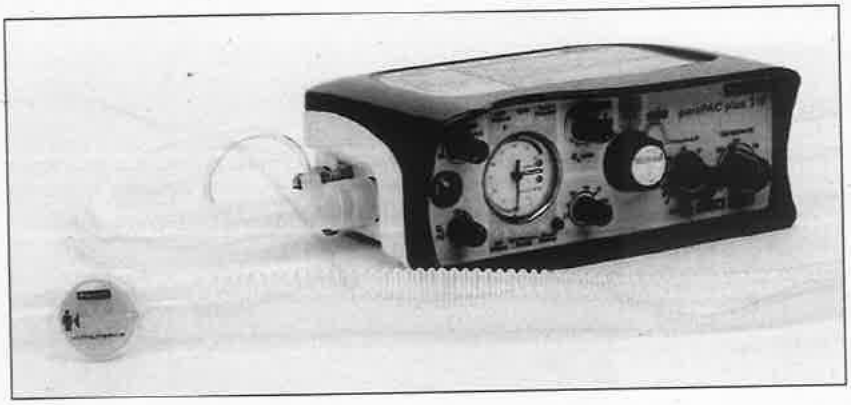
i. Parapac Plus P300

List of manufacturing facilities covered by this authorisation

i. GKN, Luton
ii. GKN, Cowes
iii. Rolls Royce

Pneupac™

paraPAC plus™ Model 300 & Model 310 Ventilator



User Manual

smiths medical