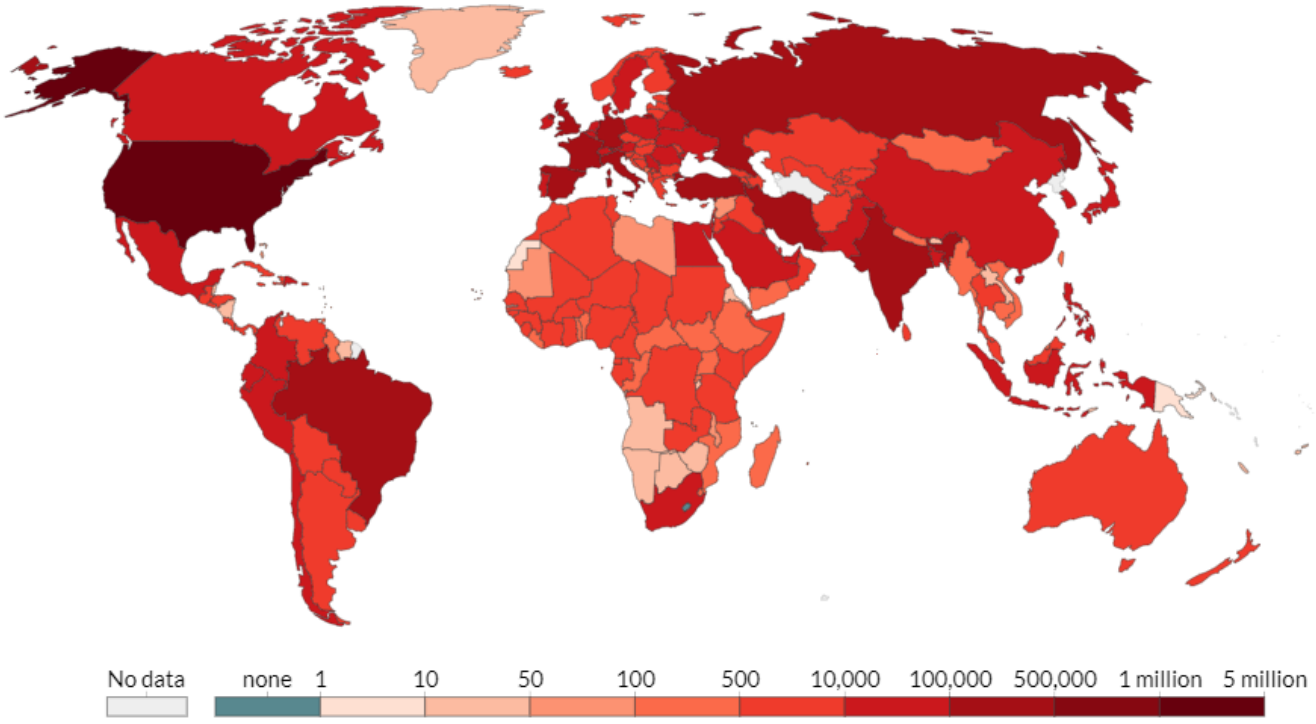
Your Tailored Approach to Emerging Markets

Ventilators

EU & FDA Standards

Newsletter IV - May 2020

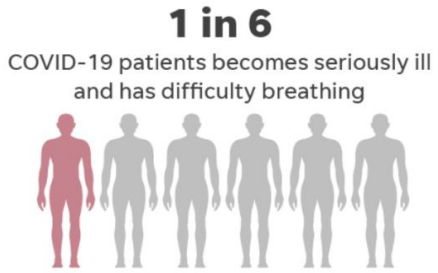


Total Confirmed Covid-19 cases, May 19, 2020

The number of confirmed cases is lower than total cases being limited testing the main reason

Ventilator are medical devices that provide mechanical ventilation to a person who is unable to breathe physically or is breathing insufficiently by moving breathable air into and out of the lungs.

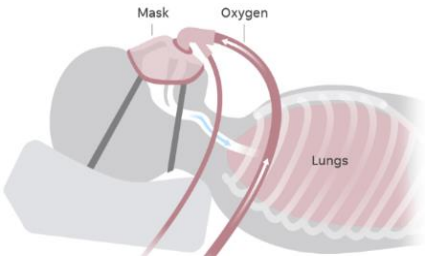
According to World Health Organization (WHO), most (about 80%) of Covid-19 affected people recover without requiring special treatment.



But around one in six affected people becomes seriously ill.

In such severe cases, the virus causes damage to the lungs, dropping body's oxygen level and making it harder to breath. To alleviate this, a ventilator is used.

Patients (of Covid-19) on ventilators have low rates of survival, as it does not treat the disease, but gives them time to fight it.



Ventilation using facemasks, nasal masks or mouthpieces may be given to people with milder symptoms, to allow air or an oxygen mixture to be pushed into the lungs. Continuous positive airway pressure or CPAP – can also be helpful in some milder cases and can avoid the need for full mechanical ventilation.

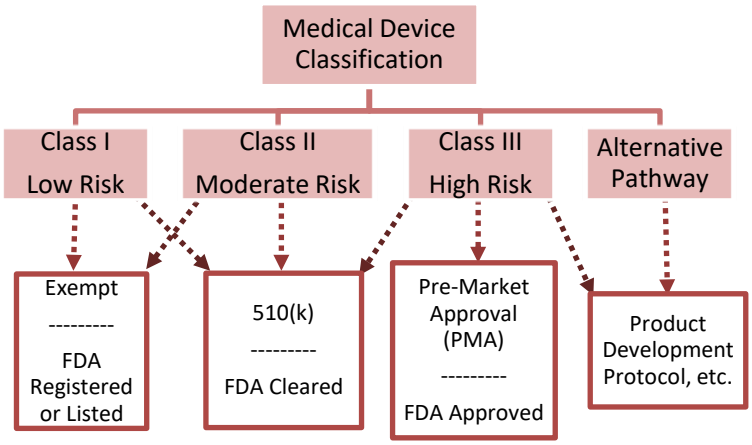
Health officials around the globe are facing critical shortage of ventilators as Covid-19 infections rising exponentially. And number of companies have responded to fulfil this requirement.

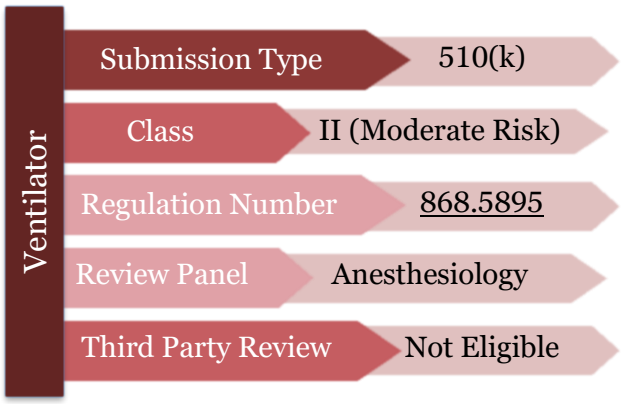
Top Ventilator Manufacturing Companies		
Becton, Dickinson and Company (U.S.)	Smiths Group PLC (U.K.)	Bunnell Incorporated (U.S.)
Koninklijke Philips N.V. (Netherlands)	ResMed Inc. (U.S.)	Cardinal Health (U.S.)
Hamilton Medical AG (Switzerland)	Getinge Group (Sweden)	Hartwell Medical Corp. (U.S.)
Fisher & Paykel Healthcare, Limited (New Zealand)	Maquet Holding B.V. & Co. KG (Germany)	Oceanic Medical Products, Inc. (U.S.)
Draegerwerk AG CO. KGaA (Germany)	Air Liquide (France)	Hillrom (U.S.)
Medtronic PLC (Ireland)	Airon Corporation (U.S.)	United Hayek Industries, Inc. (U.S.)
GE Healthcare (U.S.)	Bio-Med Devices, Inc. (U.S.)	Ventec Life Systems (U.S.)

Many other companies like Ford, General Motors, Tesla, Dyson, Toyota, Mercedes, etc. in USA and Airbus, JCB, McLaren, Dyson, Rolls Royce, Jaguar Land Rover, Unipart, Ferrari, Fiat Chrysler, Marelli, etc. in EU has responded this demand and started supporting by supplying parts, setting up the production lines, etc. for ventilators.

Revoking of the export ban on ventilators from China resulted in a few cases of fraudulent offerings with bogus contracts, forged documents and fake Weibo accounts. Doctors also informed some machines had unfamiliar design with confusing instruction manual, problematic oxygen supply, were not able to clean properly, and were built for ambulance use, not hospitals. However, majority of ventilators from China are good. We have discussed the FDA and EU CE Mark regulations for Ventilators in this paper.

FDA Standards





Regulation Classification for different Ventilators and accessories:

Ventilators			
Classification Regulation	**Device Type**	**Product Code**	**Device Classification**
21 CFR 868.5895	Ventilator, Continuous, Facility Use	CBK	II
	Ventilator, Continuous, Minimal Ventilatory support, Facility Use	MNT	II
	Continuous, Ventilator, Home Use	NOU	II
	Ventilator, Continuous, Minimal Ventilatory support, Home Use	NQY	II
	Ventilator, Continuous, Non-life supporting	MNS	II
	Mechanical Ventilator	ONZ	II
21 CFR 868.5925	Ventilator, Emergency, Powered (Resuscitator)	BTL	II
21 CFR 868.5160	Gas-machine, anesthesia	BSZ	II
21 CFR 868.5905	Ventilator, non-continuous (respirator) Including masks and interfaces under the same product code	BZD	II
	Conserver, Oxygen	NFB	II
	Device, Positive Pressure Breathing, Intermittent	NHJ	II
	Resuscitator, Manual, Non-Self-Inflating	NHK	II
21 CFR 868.5454	High flow/high velocity humidified oxygen delivery device	QAV	II
Ventilator Tubing Connectors & Ventilator Accessories			
Classification Regulation	**Device Type**	**Product Code**	**Device Classification**
21 CFR 868.5240	Anesthesia breathing circuit	OFP	I
	Anesthesia breathing circuit	CAI	I
21 CFR 868.5260	Filter, Bacterial, Breathing circuit	CAH	II
21 CFR 868.5270	Heated breathing circuit	BZE	II
21 CFR 868.5340	Cannula, Nasal, Oxygen	CAT	I
21 CFR 868.5440	Generator, oxygen, portable	CAW	II
21 CFR 868.5450	Humidifier, Respiratory Gas, (Direct Patient Interface)	BTT	II
21 CFR 868.5580	Mask, Oxygen	BYG	I
21 CFR 868.5730	Tube, Tracheal (W/Wo Connector)	BTR	II
	Airway Monitoring System	OQU	II
21 CFR 868.5895	Accessory to Continuous Ventilator (Respirator)	MOD	II
21 CFR 868.5965	Attachment, Breathing, Positive End Expiratory Pressure	BYE	II
21 CFR 868.5975	Set, Tubing and Support, Ventilator	BZO	I

Manufacturer/Supplier must meet the requirement of 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be Substantially Equivalent (SE) and states that the device can be marketed in the US. This order "clears" the device from commercial distribution.

The 510(k) Submission Process

A 510(k) submission must be submitted in an electronic format (eCopy), should be sent to CDRH's or CBER's Document Control Center (DCC), which is available on eCopy Program for Medical Device Submissions

When the DCC receives the 510(k) submission, it assigns the submission a unique control number "510(k) number," or "K number", begins with K followed by 6 digits

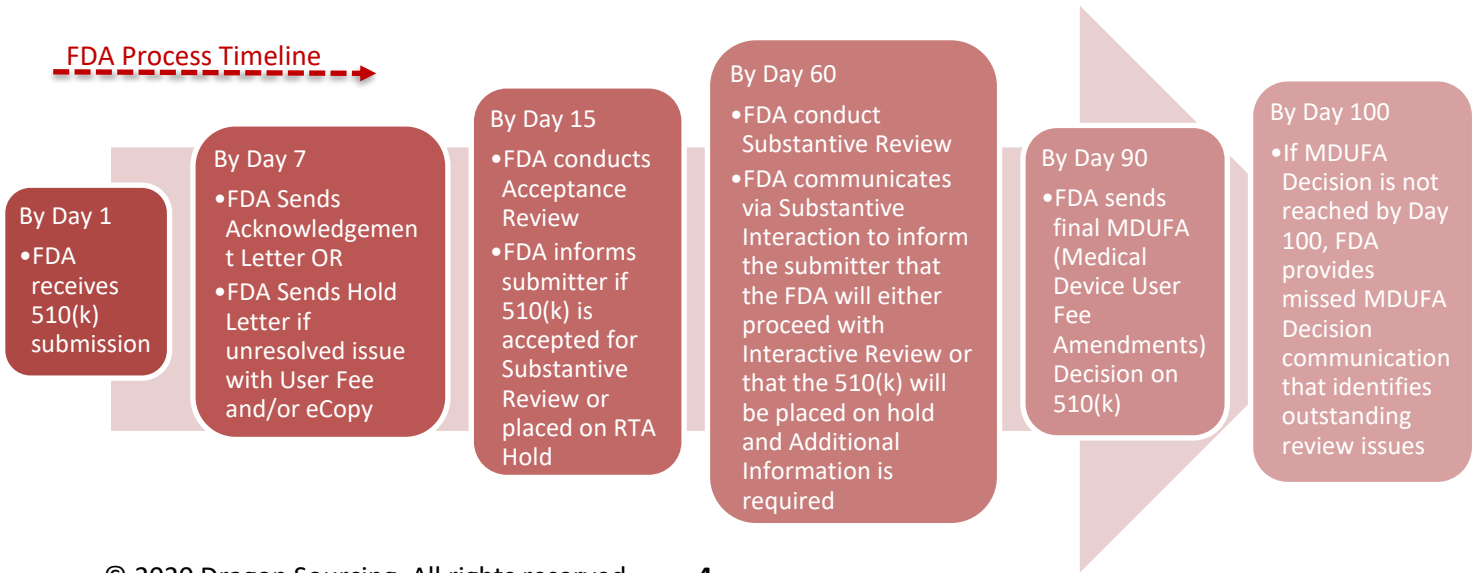
If the proper user fee has not been paid and/or a valid eCopy has not been provided, then the DCC will email a Hold Letter to the 510(k) submitter, usually within 7 days of receipt of the 510(k). Submitter needs to resolve it within 180 days. If not resolved, it will be considered as withdrawn and has to submit new 510(k) FDA marketing clearance

After the Acknowledgement Letter is sent, the DCC routes the 510(k) to the appropriate ODE or OIR Division

Within 15 days of the receipt of the submission, the submitter will receive an electronic notification of the Acceptance Review result, which will: Identify name & contact information of FDA Lead Reviewer and Indicate the status

If the Lead Reviewer sends an AI (Additional Information) Request, the submission is placed on hold. The submitter must submit the response, with a valid eCopy, to the DCC within 180 calendar days of the date of the AI Request; including the submitter's name; 510(k) number; identify the submission as Additional Information (AI) to the 510(k); date of FDA's request for AI and provide the requested information in an organized manner

When a decision is made, FDA will issue the decision letter to the submitter by email to the email address provided in the 510(k) cover letter. A 510(k) that receives an SE decision is considered "cleared." And submitter will be added in the 510(k) database, which is updated weekly.



Normally, the complete submission process (as explained above) is must to get 'FDA cleared'. But due to covid-19 pandemic, FDA has issued Emergency Use Authorization (EUA) that authorizes the Emergency use of Ventilators

Authorization Process under EUA:

Submit a Request to CDRH-COVID19-Ventilators@fda.hhs.gov that includes following information:

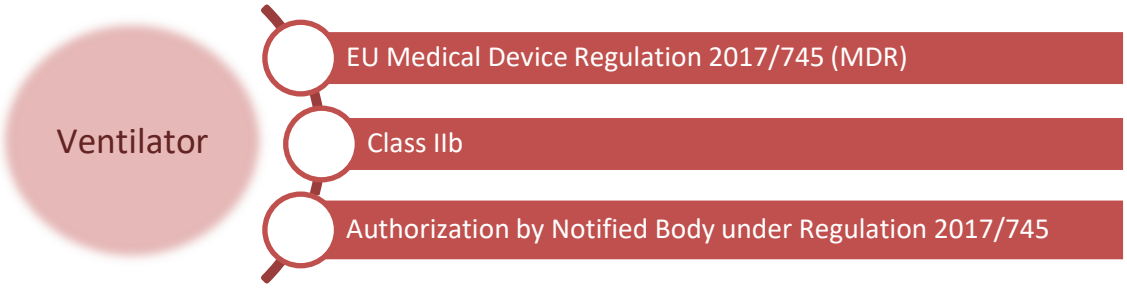
• Contact Detail, • Company Details, • US Agency Contact Details (if any), • Product Details (including brand name, model number, etc.), • Marketing Authorization in the country of origin (if any)
• A copy of the product labelling
• Whether the device currently has marketing authorization in another regulatory jurisdiction, such as European CE Mark, Australian Register of Therapeutic Goods (ARTG), Certificate of Inclusion, Health Canada Licence, or Japan Pharmaceuticals and Medical Device (PMDA) approval (including certification number, if available)
• Whether the device has been designed, evaluated, and validated in accordance with the applicable FDA-recognized standard
• Whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485 or an equivalent quality system, and manufacturer or importer has documentation of such
• Whether the device is manufactured in compliance with other internationally recognized quality management systems
• Whether the device is designed with a power supply that is compatible with US voltage, frequency and plug type standards or is accompanied with appropriate adapter to use in US
• Information sufficient to demonstrate that the device meets safety criteria, performance, and labelling

- The authorized products must be accompanied by the "Authorized Labelling" pertaining to the emergency use, which are authorized to be made available to Healthcare providers and Patients

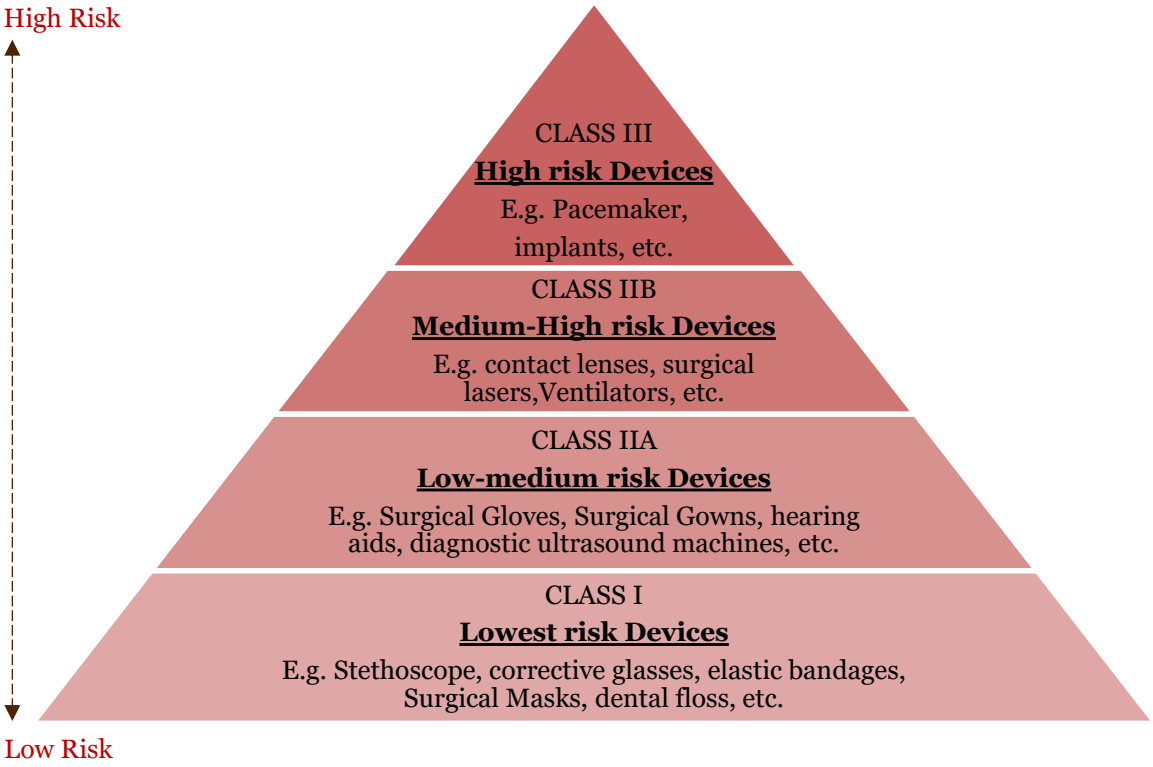
Duration of Authorization:

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of ventilators, ventilator tubing connectors, and ventilator accessories during the COVID-19 pandemic is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

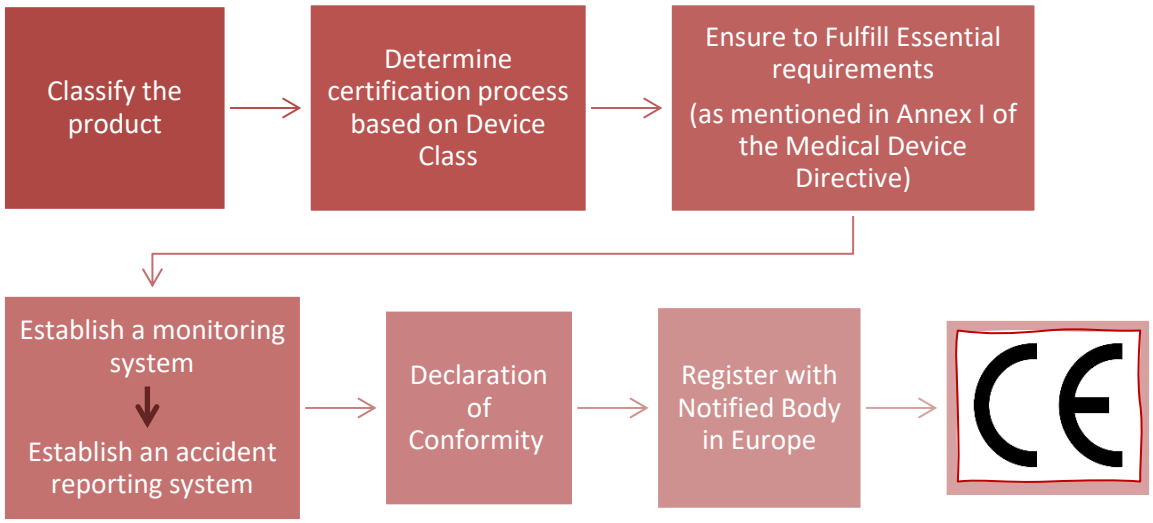
EU Regulation



Medical Devices under (Regulation (EU) 2017/745) are classified according to Risk criteria as:



Routes for CE Mark:



Normally, manufacturer or supplier needs to route through complete process (as explained above) for certified CE Mark with Authorized Notified Body.

Notified Bodies for Regulation (EU) 2017/745:

Body type	Name	Country
NB 0086	BSI Assurance UK Ltd	UK
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2409	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	Hungary
NB 1912	DARE!! Services B.V.	Netherlands
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0124	DEKRA Certification GmbH	Germany
NB 2460	DNV GL Presafe AS	Norway
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 2862	Intertek Medical Notified Body AB	Sweden
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0482	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	Germany
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0123	TÜV SÜD Product Service GmbH Zertifizierstellen	Germany

Regulation (EU) 2017/745 of 5 May 2017 on Medical Devices and Accessories, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC includes 3 years transitional period, which is due to be fully applicable in EU Member States from 26 May 2020. Although, the European Commission recently indicated that it may postpone the application of the MDA for one year considering Covid-19 outbreak.

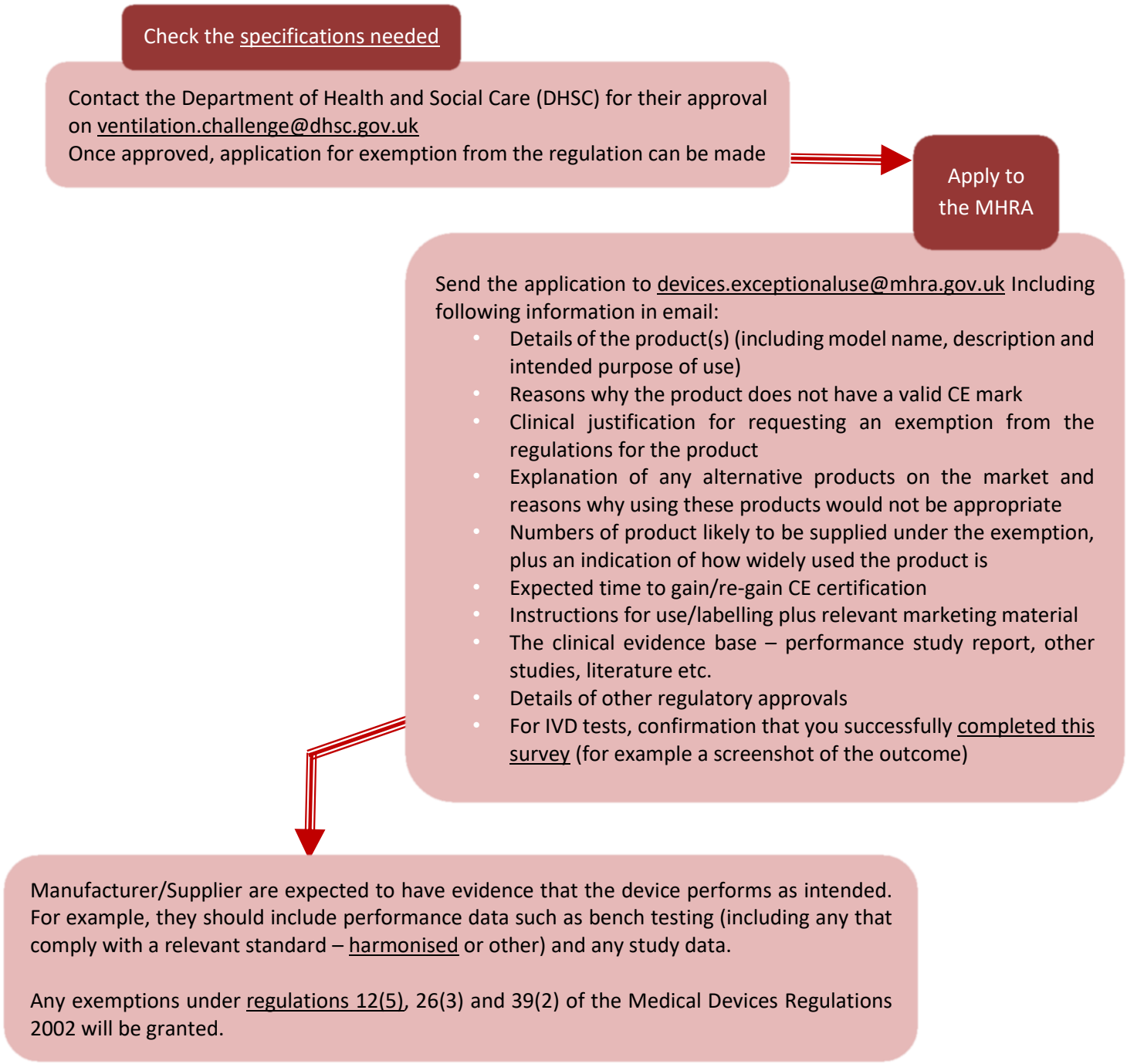
Temporary Permits

To help combat the Covid-19 pandemic, European Commission & EU Member States individually can permit non-CE mark products temporarily in EU markets.

EU Member states like Germany and UK has started allowing non-CE marked products temporarily.

- The UK Medicines and Healthcare Regulatory Authority (MHRA) issued guidelines on 'Rapidly manufactured ventilator system specifications' for the same, which also confirms that all ventilators manufactured via this route must state that the ventilator is NOT CE marked.
- This route allows for the use of non-CE marked devices in two instances:
    - A manufacturer applies to supply a medical device that does not comply with law, in order to protect a patient's life and there is no viable alternative.(This route is commonly used to treat a specific patient, but is not appropriate for mass production of ventilators)
    - The MHRA authorises a manufacturer to supply a non-compliant device in the interest of public health, under Regulation 12(5) MDR 2002

Emergency Application Process for UK:



When the current emergency has passed these devices will NOT be usable for routine care unless they have been CE marked through the Medical Device Regulations. The device must display a prominent indelible label to this effect.

Contact Us

EUROPEAN Offices

Dragon Sourcing **Paris**
57 Rue de Fontenay
92140 Clamart France
Tel::+33 (0)7 50 65 09 23
Email: bonjour@dragonsourcing.com

Dragon Sourcing **Spain**
Carrer de Biada 5, Bajos.,
08012 Barcelona, Spain
London, W1U 6PZ, UK
Tel:+ 34 689 87 09 02
Email: hello@dragonsourcing.com

Dragon Sourcing **Russia**
Aleksandri Monahovoi St 98, block 1
Moscow, 108801,Russia
Email: hello@dragonsourcing.com

Dragon Sourcing **Turkey**
Yuzuncu Yil Mah. Prof Erdal Inonu Cad..
No 10 Dalgic Sitesi B Blok Daire 30
Nilufer Bursa, Turkey
Tel: +90 505 506 86 76
Email: merhaba@dragonsourcing.com

Dragon Sourcing **South Africa**
94 Princess Avenue, Benoni 1500,
Gauteng Province, South Africa
Tel: +27 61 128 1949
Email: contact.hello@dragonsourcing.com

NORTH AMERICAN Office

Dragon Sourcing **Houston**
4532 Plantation Colony Dr
Missouri City, TX 77459
Phone: 832- 406-0281
Email: hello@dragonsourcing.com

ASIAN Offices

Dragon Sourcing **Shanghai**
Suite 1502-1503, Jin Tian Di International Mansions
998, Renmin Road – Shanghai, 200021, P.R.China
Tel: +86 21 61 41 39 55
Fax: +86 21 61 41 39 66
Email: contact.asia@dragonsourcing.com

Dragon Sourcing **Hong Kong**
10/F Guangdong Investment Tower,
148 Connaught Road Central, Hong Kong
Tel:+852 91 80 40 57
Fax: +852 25 80 24 26
Email: contact.asia@dragonsourcing.com

Dragon Sourcing **Vietnam**
Room A1.03, Hoang Anh River View
37 Nguyen Van Huong Street, Thao Dien Ward,,
District 2, HCM City, Vietnam
Tel:+84 28 6685 3589
Email: hello@dragonsourcing.com

Dragon Sourcing **Saudi Arabia**
Thiqa Bldg. 2nd Flr., Othman Ibn Affan Road (Exit 7
King Abdullah Road Al-Waha District
Riyadh, Kingdom of Saudi Arabia
Tel: +966 11 810 2252
Email: hello@dragonsourcing.com

Dragon Sourcing **India**
Suite 1502, Sorrento,
Veera Desai Road,
Andheri West, Mumbai – 400053
India
Email: contact.india@dragonsourcing.com

LATIN AMERICAN Offices

Dragon Sourcing **Brazil**
Rua Funchal, 538, 2 andar
04551-060, Vila Olímpia, São Paulo, Brazil
Tel:+55 11 9 9595 0405
Email: ola@dragonsourcing.com

Dragon Sourcing **Mexico**
PROLONGACION VASCO DE QUIROGA #
4800, Tower II Office 102 Floor 1
SANTA FE CUAJIMALPA, MEXICO CITY,
Phone +52 312 1217217
Email: hello@dragonsourcing.com

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Komal Patel
Email: komal.patel@dragonsourcing.com

 https://www.dragonsourcing.com/