



NTS Systems Development B.V.

To: [REDACTED] 5.1.2e

P.O. Box 7093

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Your ref. [REDACTED] 5.1.2e

Our ref. MCC/7415557

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Arnhem, 30 March 2020

Subject: **Quotation**

Dear [REDACTED] 5.1.2e

Thank you for your request. It is our pleasure to present you herewith our quotation for the partial of the VentilatorPAL (Freabreathing).

This offer is based on the received information on March 27 and March 30.

We trust that our quotation will meet your expectations, and look forward to your response.

Should you have any questions, please do not hesitate to contact us.

Yours sincerely,

DEKRA Certification B.V.

[REDACTED] 5.1.2e

Enclosures:

- Specification
- Order placement
- General Terms and Conditions for the Performance of Assessment and Certification Services



Specification

Product

VentilatorPAL (Freabreathing)

Service

Partial testing according to IEC 60601-1:2005, COR1:2006, COR2:2007 and AMD1:2012.

DEKRA will evaluate the product based on the following:

Clause	Test
4.3	Essential performance
4.8, 4.9, 11.3, 15.4	Ratings on critical components
4.11	Power input
5.7	Humidity preconditioning
4.6, 5.9, 8.4.2, 9.2.1	Determination of APPLIED PARTS and ACCESSIBLE PARTS
7.1.2, 7.1.3	Durability and legibility of marking
7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9	Marking, conductor colours, indicator lights and controls and ACCOMPANYING DOCUMENTS
8.5	Insulation diagram
7.3.3, 15.4.3	Batteries
8.4.3, 8.4.4	Limitation of voltage, current or energy
8.5.5.1*	DEFIBRILLATION-PROOF APPLIED PART protection
8.5.5.2*	Energy reduction
8.6.2, 8.6.5, 8.10.5	Construction of ME equipment
8.7	Leakage currents and patient auxiliary currents
8.8.3	Dielectric strength
8.8.4.1	Ball pressure
8.9	CREEPAGE DISTANCES and AIR CLEARANCES
8.10	Critical component list
9.2	Mechanical hazards associated with moving parts
9.3	Sharp edges
9.4	Instability hazards
9.6.2.1	Sound pressure level measurement (indicative measurement, on request full measurement can be performed)
11.1	Excessive temperature measurement during normal use
11.6	Spillage, cleaning, disinfection, compatibility with substances
11.8	Interruption of the power supply
13.1.2	Measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances



13.2	Single fault conditions
15.3	Mechanical strength tests

As requested this is only a partial test and not a full type testing program. Other standards might be applicable as well. For a generic ventilator the 60601-1-8, 80601-2-12 and 80601-2-55 might also be applicable; in our proposal these standards are not part of the investigation. We suggest that you contact the end-customer and IGJ for acceptance of this quoted test program.

Note to test report

Since the test report of the IEC 60601-1:2005 + A1:2012 has many references to the risk management file (risk management tables), we created a DEKRA mapping document where these references can be filled out. We ask you kindly to use this document to reduce certification lead-times and costs. The estimated costs are based on a completely filled out and approved mapping document.

Guidance, non-conformities and additional communication

In addition to the mentioned services, a reservation is made for guidance, in the event a non-conformity is found or additional communication is needed. The guidance, communication and re-evaluation of non-conformities are subtracted from this budget to reduce the delay in the project. In case we don't receive the mapping document additional fees will apply. For this we will also use this budget. You will be informed in a timely manner in case the presented costs will exceed the budget.

Note: Only the actual costs will be settled.

Investment

Partial testing as described above

When a defibrillation part is provided, the additional costs are
Guidance, non-conformity and communication budget

5.1.2b

Assumptions of this quotation:

- The test set mentioned above is based on the provided information. When more tests for this or particular standards are required additional costs will be charged.
- The equipment is classified as IP 20.
- The equipment shall not be tested for use in atmosphere other than air.
- The equipment is not suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide.
- The equipment is provided with an IEC60601 approved external power supply.
- PEMS not part of this evaluation.
- The mains plug is considered as a disconnecting device.



Samples and documentation

Information and/or components needed for testing/evaluation:

- at least 1 complete sample with all necessary components to operate the unit in a correct way for safety testing; 2 samples are preferred;
- the instructions for use (in English);
- mapping documents per service;
- all documentation that is needed for the evaluation (in English);
 - ISO 14971: complete risk management file;
 - complete filled out mapping document for the risk management file (supplied by DEKRA Certification B.V.);
- all schematics, print lay-outs and component lay-outs in PDF;
- a safety or block diagram with all separations mentioned between the different circuits including the Applied Parts;
- a list of all critical components such as: enclosure material, opto couplers, transformers, fuses, thermal cut-outs, interlocks, batteries, PCB material and lay-out and so on. (Manufacturer, type/reference number, ratings and approval marks when available e.g. CENELEC, CSA or UL approval marks. If a component is UL-recognized we like to receive the Conditions of Acceptability as well);

Procedure

To start this project, we kindly ask you to send us the following:

- order placement MCC/7415557 signed for acceptance (preferably digital);
- 100% pre-payment for the amount specified previously (following receipt of the order placement we will send you an order confirmation with pre-payment invoice);

Delivery time

The delivery time is 4 weeks after receipt of all above mentioned job necessities.

If the order is placed after the expiration of this quotation (60 days), we would like to ask you to contact us in advance. All stated delivery times are based on a positive test result.

Conditions

This quotation is subject to the DEKRA General Terms and Conditions for the Performance of Assessment and Certification Services (copy enclosed). The application of other General Terms and Conditions is hereby explicitly excluded. The acceptance of this quotation implies acceptance of the general terms and conditions referred to in this quotation.



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This quotation is based on the received documentation/information up to the date of this quotation and on the assumption that all components are certified. Possible additional costs for re-tests and/or additional work, as well as travel- and lodging costs, are not included in the amounts shown above.

Certificates are issued solely on the basis of positive investigations and test results. These are only applicable to the product under investigation and standard(s) used. A number of conditions apply to the use of certification marks. These conditions are/will be included with the agreement. Reports and certificates are issued in English language.



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Partial Testing

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Order placement

NTS Systems Development B.V. hereby accepts quotation MCC/7415557 dated 30 March 2020.

Please indicate which service(s) you require:

- Partial Testing
- Defibrillation part
- Guidance, non-conformity and communication budget

Date of approval:

Your purchase order number:

Name:

Signature:

In case the invoice must be send to a different company/department, please fill in the applicable information.

Name:

Address:

VAT number:

E-mail address:

Please send this order placement form by e-mail to:

5.1.2e	dekra.com, attn	5.1.2e
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