FACTORY INSPECTION REPORT

Inspection carried out by (Name of Inspection Body): DEKRA **Reference number of the Body carrying out the inspection:** *For page control, please write this number in the header of each page (including the attachments).*
GENERAL GUIDANCE – *The questions of this factory inspection report are based on the requirements given in Permanent Document CIG 021.* – *Guidance for the Inspector is given in Permanent Document CIG 024.* – *Both documents, PD CIG 021 and PD CIG 024 shall be taken into account during inspection.* – *Instructions to the Inspector are shown in italics.* – *The report shall be completed even if there is no production at the time of the visit.* – *For all 'NO' answers details shall be provided on the Inspector's Findings page.* – *For all 'N/A' answers rationale shall be provided as to why the item is not applicable.* – *Details should be given on Inspector's Information page.* – *This report as well as objective evidences attached to this report shall be written at least in English.*

1 GENERAL INFORMATION	
1.1 Manufacturer's registered name and factory location	
Manufacturer's registered name:	Variass Medical Systems B.V.
Street and No.:	Nipkowlaan 5
Postal code:	9207 JA
City:	Drachten
Province:	
Country:	The Netherlands
GPS-coordinates *(optional)*:	N: E:
1.2 Manufacturer's representative name and contact data	
Manufacturer's representative name:	J. Rehwinkel and B.J. Netjes
Position:	Manager Quality Assurance and ICT
Telephone:	Country Code: +31 City Code: 0598 Phone: 61 94 75
Fax:	Country Code: +31 City Code: 0598 Phone: 61 35 38
E-Mail:	j.rehwinkel@variass.nl / bj.netjes@variass.nl
1.3 The names and position held of the main persons involved in the inspection	
☒ same as mentioned under 1.2	
If not the same as mentioned under 1.2, please give details.	
Name:	
Position:	
Telephone:	Country Code: City Code: Phone:
Fax:	Country Code: City Code: Phone:
E-Mail:	

1.4 ☒ Pre-Licence ☐ Routine ☐ ENEC
☐ HAR ☐ EMC ☐ Others:

1.5 **<u>Pre-Licence only</u>: Is the information given in the Questionnaire CIG 022 Sections B.1 and B.2 (or provided in another format) accurate and complete?** YES ☐ N/A ☐ NO ☒
If 'NO', amend the Questionnaire as appropriate and attach a copy to this report.

CIG 22 B2 is filled out and signed by Variass. CIG B1 must be filled out by PlasmaMade

1.6 Inspection Details:

Certification Body requesting inspection	Inspection X of Y	File Reference No.	Product Category	Type of Product
VDE	1/1	7019406	Range hood	GUC1214 filter
		30023461		

1.7 **Name of Inspector:** T.E. van Dijk

Date of inspection: 2015-10-28
(YYYY-MM-DD)

2 Verification of purchased components and materials which have a safety implication on the certified product (Incoming Inspection)

2.1 Are materials, components and sub-assemblies verified by the Manufacturer as complying with appropriate specification? YES ☒ N/A ☐ NO ☐

2.2 Does this verification also include the verification of the Certification Marks? YES ☒ N/A ☐ NO ☐

***NOTE**:*
There shall be instructions as to which Certification Marks have to appear on the components/products in order to accept them.

Description of the procedure
(one or more boxes may be ticked)

- ☐ Rely on suppliers' out-going inspection
- ☐ Audit conducted at the suppliers' premises
- ☐ Supplier control based on Manufacturer's check list
- ☒ Conduct own incoming inspection
- ☐ Identification check
  - ☐ Checked for correct type
  - ☐ Rating
  - ☐ Comparison to a reference
  - ☐ Certification mark
- ☐ Certificate of conformity
- ☐ Others *(provide details):*

☐ Details given on Inspector's Information page

Description of the procedure or ref. of documented procedure & revision or issue date:

☒ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

2.3 If the Manufacturer relies on Certificates of Conformity, do they clearly identify the product, quantity of items covered, the specification to which the products conform, the production date and are they properly issued? YES ☒ N/A ☐ NO ☐

2.4 Is there a procedure covering the way to handle non-conforming components and materials? YES ☒ N/A ☐ NO ☐

Description of the procedure or ref. of documented procedure & revision or issue date:

☒ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

2.5 Is the procedure and the way in which it is applied satisfactory? (e.g.: components and materials clearly identified and/or segregated to prevent unauthorised use?) YES ☒ N/A ☐ NO ☐

2.6 Are records of the incoming inspection maintained and satisfactory? YES ☒ N/A ☐ NO ☐

2.7	Are records kept at least for the period between two inspection visits?	YES ☒	N/A ☐	NO ☐

3	**Production Control, Monitoring and Routine Tests**			
3.1	Are the Quality Assurance and manufacturing Personnel adequately briefed on their duties?	YES ☒	N/A ☐	NO ☐
3.2	Do they have readily available up-to-date documents, manufacturing and test instructions, photographs, drawings or samples on all those parts which have an impact on the safety of the finished products?	YES ☒	N/A ☐	NO ☐
3.3	Is there evidence that the production process ensures that the final product is identical to the certified version as described in clause 15?	YES ☒	N/A ☐	NO ☐
3.4	Is there a procedure to ensure that all products will be tested or inspected according to the Manufacturer's requirements?	YES ☒	N/A ☐	NO ☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report. Please refer to attachment no.:

3.5	Is the production process controlled at appropriate stages?	YES ☒	N/A ☐	NO ☐
3.6	Are products examined at appropriate stages of manufacture (Production Line Inspection)?	YES ☒	N/A ☐	NO ☐

***NOTE**:*
Give details of all tests and inspections performed by the Manufacturer and enter in the routine test table on the TEST DATA SHEET

3.7	Do the Routine Tests entered on the TEST DATA SHEET sufficiently cover all the Certification Bodies' requirements?	YES ☒	N/A ☐	NO ☐
3.8	Is there a procedure covering the way to handle non-conforming products?	YES ☒	N/A ☐	NO ☐

Procedure of handling non-conforming products
(one or more boxes may be ticked)
☐ Automated segregation process
☐ Manual segregation process
☐ Non-conforming products are destroyed
☒ Non-conforming products are repaired
☐ Others *(provide details):*

☐ Details given on Inspector's Information page

Description of the procedure or ref. of documented procedure & revision or issue date:
☒ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

		YES	N/A	NO
3.9	Is the procedure and the way in which it is applied satisfactory? (e.g. non-conforming products clearly identified or segregated to prevent unauthorised use?)	☒	☐	☐
3.10	Are repaired and reworked (corrected) items **again** subjected to appropriate tests/examinations in accordance with procedures?	☒	☐	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

		YES	N/A	NO
3.11	Are test records of the routine tests maintained and satisfactory?	☒	☐	☐
3.12	Are records kept at least for the period between two inspection visits?	☒	☐	☐

4 Functional Check of Test and Measuring Equipment used for Safety Tests

		YES	N/A	NO
4.1	Is there evidence that the functional check of the equipment is conducted properly, even if certified products were not in production?	☐	☒	☐
4.2	Is there a procedure describing how the functional checks shall be conducted? ☐ Automated process ☐ Manual process	☐	☒	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

		YES	N/A	NO
4.3	Is a functional check conducted with intervals which will allow previous production to be retested if incorrect functioning is detected before it leaves the factory?	☐	☒	☐
4.4	Is the proper function of the test equipment verified with a simulated failure (dummy) or by other equivalent means? ☐ Simulated failure (dummy) ☐ Test procedure according to the equipment manual ☐ Internal self-test; test program included in equipment certification ☐ Internal self-test; verified by the Inspector ☐ Others *(provide details):*	☐	☒	☐

		YES	N/A	NO
4.5	Is there evidence that the simulated failure represents the tripping limits as required? ***NOTE**:* *Except for spark testers in cable production.*	☐	☒	☐
4.6	Is there a procedure requiring appropriate actions to be taken by the operator if a functional check is found to be unsatisfactory?	☐	☒	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report. Please refer to attachment no.:

		YES	N/A	NO
4.7	Is this procedure appropriate to ensure that improperly checked products are re-tested?	☐	☒	☐
4.8	Are subsequent corrective actions taken recorded in all cases?	☐	☒	☐
4.9	Are the test records of results of functioning checks of test and measuring equipment maintained and satisfactory?	☐	☒	☐
4.10	Are records kept at least for the period between two inspection visits?	☐	☒	☐

5 Products seen in Production during visit

Identify type number and any certification mark that appeared on products seen in production at the time of the visit.
If no certified products were seen, indicate what kinds of products were manufactured at the time of visit. The manufacturing process shall nevertheless be examined.
At least one kind of product per product category and electrical insulation class shall be listed.

☐ No production
☒ Production seen for the following product:

Kind of product: Range Hood
Product category:
Insulation Class: III
Type number: GUC1214
Certification Marks: CE and TÜV

Complete TEST DATA SHEET for each kind of product per product category and electrical insulation class even if there is no production.

6 Calibration/Verification of Safety Test and Measuring Equipment

		YES	N/A	NO
6.1	Is test and measuring equipment used calibrated or verified?	☐	☒	☐

(one or more boxes may be ticked)
☐ **Verification** done by the Manufacturer by means of calibrated reference equipment
☐ **Calibration** done by:
- ☒ Laboratory accredited according to ISO/IEC 17025
- ☐ Test equipment Manufacturer/Supplier
- ☐ National metrology institute

☐ Other *(provide details):*

Provide details for at least one electrical measuring equipment:
Kind of equipment:
Type reference:
Calibration reference number:
Date of last calibration:
Calibration due date:

		YES	N/A	NO
6.2	Is reference equipment (used for verification) calibrated?	☐	☒	☐

(one or more boxes may be ticked)
Calibration of reference equipment done by:
- ☒ Laboratory accredited according to ISO/IEC 17025
- ☐ Test equipment Manufacturer/Supplier
- ☐ National metrology institute
- ☐ Other *(provide details):*

		YES	N/A	NO
6.3	Is the equipment provided with a label or similar indicating the next 'calibration due' date or another method ensuring the valid calibration/verification status?	☐	☒	☐
6.4	Do the calibration/verification records indicate that calibration is traceable to national/international standards of measurement?	☐	☒	☐
6.5	Are the records for calibration/verification of test and measuring equipment maintained and satisfactory?	☐	☒	☐
6.6	Are records kept at least for the period between two inspection visits?	☐	☒	☐

7 Handling and Storage

		YES	N/A	NO
7.1	Are the components and materials to be used for production stored and handled in such a way as to ensure that they will continue to comply with the applicable standards?	☒	☐	☐
7.2	Are the finished products stored and handled in such a way as to ensure that they will continue to comply with the applicable standards?	☒	☐	☐

8 Product Verification Tests / Periodic Tests (PVT)

8.1 Are required PVT conducted? YES ☐ N/A ☒ NO ☐

(one or more boxes may be ticked)
- ☐ NO PVT required, all questions of this section shall be marked with 'N/A'
- ☐ PVT conducted at the factory location
- ☐ PVT conducted at an external laboratory owned by the Manufacturer
- ☐ PVT conducted at an external laboratory owned by the Licence Holder
- ☐ PVT conducted by independent external laboratory
- ☐ PVT conducted by certification body's laboratory
- ☐ Others *(provide details):*

- ☐ Details given on Inspector's Information page
- ☐ Objective evidence is provided as an attachment to this Factory Inspection Report. Please refer to attachment no.:

***NOTE**:*
Describe which tests (required by the Certification Body/certification scheme) are conducted and at what sampling rate on TEST DATA SHEET – ***Product Verification Tests***

8.2 Are the tests conducted in accordance with procedures? YES ☐ N/A ☒ NO ☐

Description of the procedure or ref. of documented procedure & revision or issue date:
- ☐ Details given on Inspector's Information page.
- ☐ Objective evidence is provided as an attachment to this Factory Inspection Report. Please refer to attachment no.:

8.3 Is appropriate equipment that is required for conducting tests available? YES ☐ N/A ☒ NO ☐

8.4 Are the tests described in TEST DATA SHEET – **Product Verification Tests** in compliance with the requirements of the Certification Schemes and/or the requesting Certification Body? YES ☐ N/A ☒ NO ☐

8.5 Is there a procedure requiring actions to be taken if PVT are found to be unsatisfactory? YES ☐ N/A ☒ NO ☐

Description of the procedure or ref. of documented procedure & revision or issue date:
- ☐ Details given on Inspector's Information page.
- ☐ Objective evidence is provided as an attachment to this Factory Inspection Report. Please refer to attachment no.:

8.6 Are the records of product verification tests maintained and satisfactory? YES ☐ N/A ☒ NO ☐

8.7 Are records kept at least for the period between two inspection visits? YES ☐ N/A ☒ NO ☐

9 Void

10 Corrective actions in response to Inspector's evaluation

If there were any unsatisfactory findings entered in the previous inspection report, have these been corrected? YES ☐ N/A ☒ NO ☐

***NOTE**:*
If the Inspection Report is not available, tick 'N/A' and give details.
If there were no findings at the previous inspection report, tick 'N/A' as well.

Provide details of each unsatisfactory finding and how each has been resolved.

11 Quality Management System

If the Manufacturer has a Quality Management System certified or assessed by an accredited Body, provide details of QMS standard, scope, name of certification body and certificate expiry date or provide copy of the certificate.

☐ Quality Management System NOT certified
☒ Quality Management System certified by an accredited Body
☐ Quality Management System certified by a non-accredited Body
☐ Copy of the certificate provided as appendix to this report

Details of QMS standard: ISO 9001-2008
Does the scope covers the production of the certified product:
☒ YES ☐ NO

Name of certification body: DEKRA
Certificate no.: 2119591
Certificate issued date: 2008 sept 12
Certificate expiry date: 2017 sept. 01

12 Manufacturer's self-assessment of the manufacturing and control process of certified products (Former: Audits of the Quality System)

12.1 Does the Manufacturer regularly check that all procedures as required by the Certification Body(is) and the harmonised inspection scheme (CIG 021) are followed? YES ☒ N/A ☐ NO ☐

12.2 Are records regarding results and actions taken available? YES ☒ N/A ☐ NO ☐

***NOTE**:*
The use of CIG 023 to document the results of the self-assessment is acceptable.

12.3 Are the personnel carrying out above required checks appropriately trained and independent of the process being assessed? YES ☒ N/A ☐ NO ☐

12.4 If there were any unsatisfactory findings identified from the Manufacturer's self-assessment of the manufacturing and control process of certified products, have these been corrected? YES ☒ N/A ☐ NO ☐

13 Void

14 Technical Complaints

The Manufacturer shall record any technical complaint regarding the certified product.
The questions in this section shall be answered even if no customer complaints have been received. In this case the questions shall be applied to the process.

14.1 Is there a procedure regarding how to handle customer complaints? YES ☒ N/A ☐ NO ☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☒ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

14.2 Are the received complaints reviewed on a regular basis regarding whether they are related to single errors or system errors? YES ☒ N/A ☐ NO ☐

☐ Actual case checked ☐ Procedure checked

14.3 Are corrective actions and decisions regarding customer complaints recorded? YES ☒ N/A ☐ NO ☐

☐ Actual case checked ☐ Procedure checked

14.4 Is the originator of the complaint informed about the handling and the result of the complaint? YES ☒ N/A ☐ NO ☐

☐ Actual case checked ☐ Procedure checked

14.5 Are the records of customer complaints maintained and satisfactory? YES ☒ N/A ☐ NO ☐

14.6 Are records kept at least for the period between two inspection visits? YES ☒ N/A ☐ NO ☐

15 Certified Products and Changes to Certified Products

15.1 Is reference about the certified version available? YES ☒ N/A ☐ NO ☐

(one or more boxes may be ticked)
☒ Set of drawings ☒ Parts list ☒ Product description
☐ Reference sample ☒ Photo-documentation ☐ Other specification *(provide details):*

☐ Details given on Inspector's Information page

15.2 Is this reference under control of the Licence Holder? YES ☒ N/A ☐ NO ☐

15.3 Is there a procedure ensuring that no changes to the construction of certified products will be implemented prior to acceptance by the Licence Holder? YES ☒ N/A ☐ NO ☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

15.4 If the Manufacturer is also the Licence Holder: Is there a procedure ensuring that constructional changes of the certified product will be made only after approval by the Certification Body?

YES	N/A	NO
☐	☒	☐

Description of the procedure or ref. of documented procedure & revision or issue date:
☐ Details given on Inspector's Information page.
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

15.5.1 Have changes been made to the certified product since last inspection?

☐ YES ☒ NO

- *If 'YES', answer the question below.*
- *If 'NO', tick 'N/A' below.*

15.5.2 Have these changes been made with the authorisation of the Licence Holder?

YES	N/A	NO
☐	☒	☐

16 Selection and Shipping of Re-Examination Sample(s)

Regarding samples requested by the Certification Body(ies) please refer to the table IDENTIFICATION OF SELECTED SAMPLES and enter details as appropriate.

16.1 If selection of samples for re-examination is required, have the required samples been selected?

YES	N/A	NO
☐	☐	☒

The reasons why no samples were selected during the inspection:
(one or more boxes may be ticked)
☐ None required by the certification body:
☐ No production, no stock:
☐ Build to clients' order
☐ No access to warehouse
☐ Warehouse not at Manufacturer's location
☐ Manufacturer has been instructed to send re-examination samples:
☐ Others *(provide details):*

☐ Details given on Inspector's Information page
☐ Objective evidence is provided as an attachment to this Factory Inspection Report.
Please refer to attachment no.:

16.2 If the selected sample(s) do not bear the Certification Mark then provide the reason for selection in the table IDENTIFICATION OF SELECTED SAMPLES.
(one or more boxes may be ticked)

☐ Type reference is mentioned on the certification bodies certification list
☐ Mark is applied on the package, catalogue or by other means
☐ Special sample selection order
☐ Others *(provide details)*
☐ Details given on Inspector's Information page
☐ Objective evidence is provided as an attachment to this Factory Inspection Report. Please refer to attachment no.:

17 Inspector's Evaluation

17.1 *List your findings on the Inspector's Findings page by referencing the applicable clauses in this report (including comments, recommendations, etc.) and explain them to the Manufacturer. If possible, indicate also the corrective actions the Manufacturer intends to take*.

17.2 *Give your recommendations by ticking the appropriate box.*

1	No unsatisfactory findings	**Grant or continue certification.**	☒
2	Minor unsatisfactory finding(s)	**Manufacturer's corrective action(s) will be checked at next visit. Grant or continue certification.**	☐
3	Major unsatisfactory finding(s) Safety not directly affected	**Manufacturer shall confirm corrective action(s). Grant or continue certification.** Special or early routine inspection recommended for checking corrective action(s).	☐
4	Critical unsatisfactory finding(s) **Safety directly affected**	**Certification refused/suspended and repeated factory inspection recommended after the Manufacturer has confirmed implementation of corrective action(s).**	☐

17.3 Attachments:
For page control, write the reference number in the header of each attachment page.

☒ PD CIG 023 Appendix 1 – Signature page	No. of pages:	1
☐ PD CIG 023 Appendix 2 – ENEC Appendix	No. of pages:	
☒ Copy of Quality Management Certificate	No. of pages:	1 of 1
☒ Others	No. of pages:	1 of 1

Total no. of pages of this report including all attachment pages: 19
(Front pages to be excluded from page numbering!)

A copy of this report shall be provided to the undersigned contact person who should be aware of the contents and sign for its receipt.

☒ Printed copy provided ☒ Electronic copy provided

Content of this report including findings as documented on Inspector's Findings page (if any) have been explained by the Inspector to the Manufacturer's contact person.

Inspection duration: 3 hours

The responsibility for ensuring that a product is manufactured in accordance with the standard to which it was originally approved rests with the Licence Holder.

Date: 2015-10-28	Date: 2015-10-28
Inspector's name (printed letters): T.E. van Dijk	Contact person's name (printed letters): J. Rehwinkel
Signature:	Signature:
☒ For signatures see attached signature page.	

Inspector's Findings page

Related clause number of this report:	Inspector's points requiring corrective action from the Manufacturer *Use separate Supplementary Page for different Certification Bodies if necessary.*
	None

Inspector's Information page

Related clause number of this report:	*Use separate Supplementary Page for different Certification Bodies if necessary.*
2.2	Procedure Received materials is described in PP06-01 rev 4 Procedure check Incommingmaterials is described in PP06-02rev3 The housing for the filter is received from PlasmaMade.
3.2	The product is described in PIM The production instruction is given in GUC1214filter rev 1.9. The production is described in text and with pictures.
3.2/3.8	The test instructon is given in GUC1214filter rev 1.1
6	For the Range hood GUC 1214 is no calibrated test equipment necessary. The way of calibration test equipement is described in OP02-01. All the test equipment is calibrated outside.
8	The finished products are send to PlasmaMade
12	The management review is described in BZ04-01 rev 1 Internal audits are described in BZ01.01 rev 3
15	Changing products is described in OP04.02 rev 4 Changes are made by using ECform.
16.1	Untill now there is no production with VDE
17.3	Added documents ISO certificate and form CIG 22 B2. CIG22 B1 must be filled out by PlasmaMade

TEST DATA SHEET – Product Verification Tests / Periodic Tests (PVT)

***NOTE**:*
CB stands for Certification Body or Certification Scheme

CB	Product, Sampling Rate, Standards Clause or Test-Parameters, Results
	N/A

TEST DATA SHEET – Routine Tests

☐ No production	
☒ Production seen	Certification mark: CE and TÜV
Product Category:	Kind of product: Range hood
Type number: GUC1214	Electrical Insulation Class: III
Rated voltage: 12V	CB Routine Test Requirement:

TESTS		% check	Test value applied	Time	Factory limits applied:	Failure indicated by	Remarks	W / R
a	Earth continuity	N/A	V A	s	Ohm (max.)			
b	Insulation resistance		V d.c.	s	MOhm (min.)			
c	Leakage current		V		mA (max.)			
Dielectric strength	Basic insulation	N/A	V	s	mA (max.)			
Dielectric strength	Supplementary insulation		V	s	mA (max.)			
Dielectric strength	Reinforced insulation		V	s	mA (max.)			
e	Load deviation							
f	Functional test							
	Visual	100						

e Indicate method used (hot/cold, at mains voltage, low voltage resistance check, etc.).
f Are all controls and components checked during the test?
W = Test witnessed by the Inspector; R = according to records

IDENTIFICATION OF SELECTED SAMPLES	at Manufacturer:			Date:		
Selected for	Label No.	Quantity	Product/Type/Technical data	Licence No.	Production period	Code letters
VDE	N/A		N/A			☐P ☐F ☐S ☐T ☐A
						☐P ☐F ☐S ☐T ☐A
						☐P ☐F ☐S ☐T ☐A
						☐P ☐F ☐S ☐T ☐A
						☐P ☐F ☐S ☐T ☐A
						☐P ☐F ☐S ☐T ☐A
						☐P ☐F ☐S ☐T ☐A

Code letters:

P = Sample from Production

S = Stock

F = Forwarded by the Manufacturer

T = Transported to the Certification Body by the Inspector

A = Shipped by the Inspection Agency