Product: Sauerstoffsensoren / Oxygen Sensors

Description:

Model: Medizinische Sauerstoffsensoren / Medical Oxygen Sensors

Type: OOMXXX-X (Except OOM109-X)

Manufacturer:

ENVITEC-WISMAR GMBH
ALTER HOLZHAFEN 18
D-23966 WISMAR

Das Gerät/System besteht aus den folgenden **Komponenten**
*The device/system encompasses the following **components**:*

- This clinical evaluation refers to the following medical O2 sensors: OOMXXX (Except. OOM109)

Intended Use:

The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications:

- Sensing device for oxygen in control device of oxygen concentrators
- Sensing device for oxygen in medical ventilators
- Sensing device for oxygen in anaesthesia equipment
- Sensing device for oxygen in incubators

The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases.

Functional Description:

EnviteC Medical Oxygen Sensors are based on the principle of electro-galvanic sensors. They are constructed in a plastic housing containing two electrodes - a precious metal cathode and an anode immersed in a liquid electrolyte medium. Electrically the device resembles a very low voltage battery cell. A gas permeable diffusion membrane provides the interface to the gas sample. The oxygen gas is reduced on the sensing electrode (cathode) and the anode is oxidized. The resulting current produces an external electrical voltage signal on the load resistor that is proportional to the conversion of the oxygen. The sensor signal is temperature dependent and typically compensated with an internal temperature-compensating resistor network.

1 Performance of Clinical Evaluation

The evaluation is based on the following documents:

- European Medical Device Directive 93/42/EEC (last change 2007/47/EEC) Annex X
- MEDDEV2.7.1 Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies Coordination of Notified Bodies Medical Device (NB-MED) on Council Directives 90/385/EEC and 93/42/EEC

Für die Klinische Bewertung wurde folgender Weg gewählt
The following path is chosen for the clinical evaluation:

☒ Zusammenstellung und Auswertung relevanter wissenschaftlicher Literatur, Normen und Spezifikationen mit anschließender kritischer Bewertung. (Literaturweg)
Compilation and analysis of clinical data from relevant scientific literature, standards and specifications with subsequent critical appraisal (Literature search)

☐ Klinische Prüfungen / Studien und Tests gemäß EN ISO 14155 (Klinische Prüfung) [1]
Clinical investigations and testing according to EN ISO 14155 (Clinical Investigation)[2]

☒ Zusätzlich wird das Produkt in Gebrauch und Leistung aus den Markterfahrungen heraus bewertet und handelsüblichen vergleichbaren Produkten für medizinische Zwecke gegenübergestellt. (Marktstudie – insbesondere für FDA-Zulassung)
Additionally, the product is evaluated in terms of usability and experience from the market and is compared with standard equivalent products for medical applications. (Clinical experience – for FDA clearances/approvals in particular)

☐ Sonstige / *Other:* .....

1.1 Nachweis über die Qualifikation des Personals / Evidence of Qualification of Staff

Table 1. Bewertungsteam / *Appraisal team*

Team of clinical evaluation	Qualification (Factual knowledge about topic under discussion plus length of service, if applicable)
Marko Sprössel	Mechanical Engineer, More than 17 years experience in development of medical products
Maik Lingies	Electrical Engineer, More than 17 years experience in development of medical products
Christa Dumschat	PhD in Chemistry, More than 15 years experience in development of medical products
Eleonore Helms	Quality Manager, More than 10 years experience in automotive, electronics and medical industries Certified Manager Regulatory Affairs Medical Device International Certified 6 Sigma Black Belt

Bemerkung: Der Literaturweg und die Auswertung der Marktdaten soll von Personal durchgeführt werden mit angemessener Qualifikation und Erfahrung bezüglich Auslegung und Anwendung des Produktes.

Remark: Literature search and appraisal of pre- and post market clinical data to be performed only by suitably qualified staff experienced in the design and application of the product.

2 Literaturweg / Literature Review

Dieser Weg der klinischen Bewertung basiert auf einer Zusammenstellung und Auswertung der relevanten wissenschaftlichen Literatur, Normen und Spezifikationen mit anschließender kritischer Bewertung.
This approach of clinical evaluation is based on the compilation and appraisal of clinical data from relevant scientific literature, standards and specifications with subsequent critical evaluation.

2.1 Zielstellung / Targeting

Zielstellung dieser Bewertung ist es, umfassende Vorgaben für das Medizinprodukt, seiner sicheren Anwendung, Leistung, Auslegungsmerkmale und Zweckbestimmung sowie seines Umfeldes zu identifizieren. Die erfasste Literatur definiert möglichst vollständig alle Vorgaben für die Sicherheit und Leistung des Medizinproduktes. Es werden keine uns bekannten Publikationen bezüglich Anwendung, Risiken, Nebenwirkungen zum Produkttyp und seiner Zweckstimmung vorenthalten.
The objective of this evaluation is to identify comprehensive specifications for the medical device, its safe use, performance, design features and intended use as well as environmental conditions. The literature used defines as completely as possible all specifications for the safety and performance of the medical device. No known publications with regard to the use, risks, side effects of the product type nor of its intended use are withheld.

[1] Die Klinische Prüfung ist gesondert bei den zuständigen Behörden (DIMDI, Ethikkommission usw.) anzumelden und unterliegt besonderen Regeln für die Durchführung und Auswertung.
[2] Clinical trials must be applied for separately with the competent authorities (DIMDI, ethical review committee etc.) and are subject to special rules for implementation and evaluation.

2.2 Identifikation der Literaturstellen / Identification of Literature Sources

Table 2. Literaturstellen / Literature sources

Literature source	Type of literature	Refers to: Safety, performance data, design features, application, intended use as well as environmental conditions*
I. ISO 80601-2-55:2011	Norm	Safety, performance
II. ISO 80601-2-12 (2011)	Norm	Performance
III. ISO 80601-2-13	Norm	Performance
IV. ISO 80601-2-69:2014-12	Norm	Performance
V. IEC 60601-1:2012	Norm	Safety, performance
VI. Anesthesia Equipment Principles and Applications Jan Ehrenwerth James Eisenkraft, James Berry, 2013 Elsevier B. V.		
VII. MAUDE Database FDA	Medical database	Product code CCL from 2005 to August 2015 (Oxygen gas analyzer)
VIII. CEcert 2015: Test report ISO 80601-2-55; Envitec Oxygen Sensors	Unpublished literature	Safety, performance
IX. Beatmung: Indikationen - Techniken - Krankheitsbilder 2012 Springer Reinhard Larsen, Thomas Ziegenfuß	Professional literature	Application, performance
X. Medizintechnik: Verfahren - Systeme - Informationsverarbeitung 2006 , Springer, Rüdiger Kramme Kapitel Kap.56 Inkubatoren	Professional literature	Application, performance
XI. Medizintechnik: Verfahren - Systeme - Informationsverarbeitung 2006 , Springer, Rüdiger Kramme Kapitel Kap.21 Langzeitbeatmungsgeräte für die Intensivtherapie	Professional literature	Application, performance

Bewertung / *Evaluation:* Typ der Literatur / *Type of literature* **:

a) Medizinische Datenbanken / *Medical database*,
b) Klinische Studie / *Clinical trial*,
c) Richtlinien, Normen / *Guidelines, directives, standards*
c) Fachliteratur / *Professional literature*,
c) andere Publikationen *other publications*,
d) unveröffentlichte Literatur / *literature not published*

* nicht zutreffendes bitte streichen / *Delete, if not applicable*

** die für die Literaturstellen verwendete Nummerierung entspricht ihrer Bedeutung / Wichtung für die Bewertung / *The numbering/ranking used for the literature sources corresponds to its relevance / weighting for evaluation*

2.2.1 Zuordnung der Literaturstellen zur beschriebenen Anwendung und Zweckbestimmung
Assignment of literature sources to application and intended use described

Table 3: Die folgende Tabelle vergleicht die Zweckbestimmungen aus der Literatur mit der Produktofferte
The following table compares the intended use from literature with the offered product's intended use

Literature source No.	Aufgeführte Anwendung/Zweckbestimmung laut Literaturstelle (Indikation, Kontraindikation) *Listed application/intended use from literature source (indication, contra-indication)*	Offerierte Anwendung zur Zweckbestimmung des Produktes *Offered application for product's intended use*
I	RESPIRATORY GAS MONITOR (RGM)	Oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures for system monitoring
IV	Oxygen concentrator equipment	Sensing device for oxygen in oxygen concentrator equipment for system monitoring
X	Oxygen sensor Incubators	Sensing device for oxygen in incubators
III/VI	Oxygen sensor in Anesthesia Equipment	Sensing device for oxygen in anaesthesia equipment for system monitoring
II/IX/XI	Oxygen sensor in critical care ventilators	Sensing device for oxygen in medical ventilators for system monitoring
VII	Oxygen gas analyzer	Oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures for system monitoring

Bewertung /Appraisal:

☒ Die für das Produkt beabsichtigten Anwendungsbereiche und Einschränkungen sind in der oben aufgeführten Literatur vollständig beschrieben.
The intended use of the product and its limitations of use are fully described in the above literature.

☐ Folgende Zweckbestimmungen gehen über die o. a. Literatur hinaus bzw. bilden eine Einschränkung: */ The subsequently listed intended uses exceed the above literature or limit it accordingly:*

- XXXX

2.2.2 Zuordnung der Leistungsdaten, Auslegungsmerkmale und Sicherheitsanforderungen
Assignment of performance data, design features and safety requirements

Table 4: In folgender Tabelle sind die notwendigen Leistungsdaten aus der Literatur den verifizierten/ validierten Leistungsdaten des Produktes gegenübergestellt.
The following table shows a comparison of required performance data from literature with those of verified/validated performance data of the product.

Geforderte Leistungsdaten: *Required performance data:*	Anforderungen / Werte: *Requirements / Values:*	Literaturstelle Nr.: *Literature source No.:*	Leistungsdaten des Produktes: *Performance data of the product:*
Measurement accuracy O_2	Volume fraction of 2.5% + 2.5 % of gas level	I	Meets ISO 80601-2-55 requirements
Drift of measurement accuracy	Not more than volume fraction of 2.5% + 2.5 % of gas level in 6h	I	Meets ISO 80601-2-55 requirements
Measurement accuracy of gas readings for gas mixtures	According to ISO 80601-2-55:2011	I	Meets ISO 80601-2-55 requirements
Stability of marking and labels during cleaning and disinfection	according to IEC 60601-1:2012; section 7.1.3	II	According to requirements (see VIII)
Shock and vibration for professional transportation	According to IEC 60600-2-27:2008		According to requirements (see VIII)
Measurement range	18-100% O_2 V/V	I u. VI	0-100% O_2 V/V
Humidity	Incubator 30 to 99% ventilator dry air	X; XI	0 – 99% RH non condensing – 0.03 % rel. per % RH at 25°C
Pressure (open circuit)	125 hPa above ambient pressure	II u. III	600 hPa – 2000 (0 – 1500 mBar O2)

Bewertung / Appraisal:

☒ Die für die Zweckbestimmung notwendigen Leistungsdaten, Auslegungsmerkmalen und Sicherheitsanforderungen werden durch das Produkt hinreichend abgedeckt.
The required performance data, design features and safety requirements for the intended use are sufficiently covered by the product.

☐ Folgende Abweichungen/Ergänzungen haben keinen Einfluss auf die sichere Verwendung:
The following deviations/additions have no adverse influence on the safe use:

- XXXX

2.2.3 Bewertung der erkannten Produktrestrisiken in den Literaturstellen
Evaluation of the product's known residual risks from citations

Table 5: Gegenüberstellung der analysierten Restrisiken aus der Risikoanalyse und ihrer Beantwortung in der aufgeführten Literatur
Comparison of residual risks analyzed in the risk management file and their mitigation from the cited literature:

Con-sec. no.	Potential residual risk	Citation no.:	
		VII	VI
1.	Cross infection after use with another patient	No problem in class CCL reported	p.176
2.	Wrong measurement due to temperature or pressure outside of the specification	No problem in class CCL reported	p. 575

Bewertung / Appraisal:

☒ Die mit dem Produkt verbundenen Restrisiken sind gemäß o. a. Literatur allgemein anerkannt und vernachlässigbar gegenüber dem klinischen Nutzen.
The residual risks of the product are generally known/recognized according to the above citations and can be neglected due to its clinical benefit.

☐ Folgende Restrisiken weichen vom anerkannten Stand der Technik ab:
The following residual risks deviate from the recognized state of the art:

- XXXX

2.3 Zusammenfassende Literaturbewertung / Conclusion of Literature Appraisal

Die Literatur beweist den klinischen Nutzen des Produktes. Die mit dem Produkt verbundenen (Rest-) Risiken sind auf ein vertretbares Maß (anerkannter Stand der klinischen Praxis) reduziert.
Die ausgewählte Literatur ist ausreichend, die Konformität des Produktes mit den Grundlegenden Anforderungen der Richtlinie 93/42/EWG zu bewerten.

The literature search proves the clinical benefit of the product. The residual risks of the product are minimized to an acceptable level (recognized state of clinical practice).
The selected literature is sufficient to evaluate the product's conformity with the Essential Requirements of the European Directive 93/42/EEC.

3 Zusammenfassung der Klinischen Studien, Prüfungen und Tests / Conclusions from Clinical Investigation and Testing

Titel der Studie: *Title of investigation:*	
Identifikation der Produkte (Typ, Model, Seriennummer, verwendetes Zubehör usw.) *Identification of product/s (type, model, serial number, used accessories etc.)*	
Name des Austraggebers/Sponsors: *Name of sponsor:*	
Prozedur / *Procedure:* Die Studie wurde entsprechend der Vorgaben der ISO 14155 durchgeführt. *The trial was performed according to ISO 14155.*	
Ziel der Studie: *Rationale of investigation:*	
Studienleiter: *Leader of investigation:*	
Studienorte: *Site of investigation:*	
Studienzeitraum: *Period of investigation:*	
Materialien und Methoden: *Materials and methods:*	
Zusammenfassung des Studienplanes: *Summary of investigation plan:*	
Ergebnisse: *Results:*	
Diskussion und Schlussfolgerungen: *Discussion and conclusions:*	
Autor des Reports / Author of report:	
Date of report:	

4 Vergleich mit handelsüblichen etablierten Produkten / Comparison with standard established products

4.1 Listung der Vergleichsprodukte für die Klinische Bewertung
List of comparative products for clinical evaluation:

One sensor type from Envitec was chosen and compared with compatible competitive sensors.

Table 6:

Product, performance data	Equivalent product I	Equivalent product II	Comments
Hersteller / *Manufacturer:*	City Technology	Teledyne Analytical Instruments	EnviteC
Model:	MOX-9	R24	OOM 202 (as example)
Revision der GA *Revision of instructions for use*	None found	C71746 Rev.4	Rev.1 2015
Revision der Kurzanleitung *Revision of brief instruction*	Product Data Sheet Issue 6, Feb.14	Spec Control DWG Oxygen sensor Class R24 Rev.10 (23.04.2002) retrieved at Sept. 2015	Product Data Sheet 010/2006
Zulassungs-Nr. *Accreditation number*	FDA K041773	FDA K001095	FDA K082655
Product code (UMDNS ...)			13-538
Intended use	These sensors are designed to be used to monitor the partial pressure of oxygen in anaesthesia (not including xenon), critical care, neonatal incubators and general oxygen monitors.	Teledyne medical oxygen sensors are intended to accurately measure the concentration of oxygen in a mixture of gases used in medical applications. The sensors are the oxygen-sensing component. Intended for sensor replacement of finished medical devices such as an oxygen monitor that is used to monitor the oxygen concentration in a patient's breathing environment.	The EnviteC Medical Oxygen Sensors are intended as oxygen-sensing component of an oxygen analyzer that measures oxygen concentration in breathing gas mixtures in the following applications: - Sensing device for oxygen in control device of oxygen concentrators - Sensing device for oxygen in medical ventilators - Sensing device for oxygen in anesthesia equipment - Sensing device for oxygen in incubators The use is limited to system monitoring. The sensors are not suited for breath by breath analysis of breath gases.
Patient population	The target patient population consists of those patients who require the oxygen concentration in their breathing environment to be monitored.	Not found	The target patient population consists of those patients who require the oxygen concentration in their breathing environment to be monitored.
Application	See intended use	See intended use	See intended use
...			

Bemerkung: Für die klinische Bewertung dürfen nur zugelassene Vergleichsprodukte mit vergleichbarer Zweckbestimmung und Anwendungsbereich herangezogen werden.

Remark: *Clinical evaluation allows only approved equivalent products with comparable intended use and application range.*

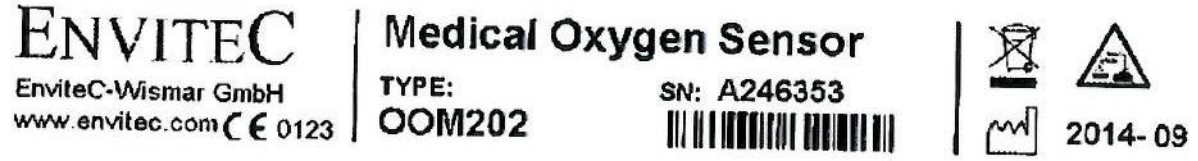
4.2 Vergleich der Produktinformationen (Anwendungsbereich, Label, Gebrauchsanweisung usw.)
Comparison of product information (range of application, label, instructions for use etc.)

Table 7: Produktinformationen, Sicherheitshinweise und Kennzeichnungen
Product information, safety advice and labelling

Product, performance data:	Equivalent product I	Equivalent product II	Product of clinical evaluation	Comments
Safety advice in accompanying documents:	Connection should be made via recommended mating parts only. Soldering to the sensor will damage it and invalidate the warranty. However, it is important that exposure to high concentrations of solvent vapours is avoided, both during storage, fitting into instruments and operation. When using sensors with printed circuit boards (PCBs), degreasing agents should be used before the sensor is fitted. Do not glue directly on or near the CiTiceL as the solvent may cause crazing of the plastic. The sensor is not suitable for sterilisation by steam or exposure to chemicals such as ethylene oxide or hydrogen peroxide. When installing the sensor, it must only be screwed in hand-tight and a gas tight seal ensured. Spanners and similar mechanical aids may not be used, as excessive force may damage the sensor thread. MedieLs contain metal and may be susceptible to RFI or EMI. For further information please contact City Technology.	Inspect the sensor for any physical damage or electrolyte leakage. If the sensor is defective DO NOT USE. The sensor electrolyte is caustic. Do not let it come in contact with the skin or eyes.	It is the responsibility of the user to determine the suitability for use of the sensor. Follow the instructions for use of the oxygen analyzer and for replacement of oxygen sensor. To avoid cross infection please follow strictly the instructions of the oxygen analyzer manufacturer. Refer to the oxygen analyzer operation manual to determine any needed preoperative checks. Sensor contains encapsulated by a housing, lead (Pb), lead oxide (PbO) and concentrated potassium hydroxide solution (between 2 and 5 mol / L). Lead and lead oxide are toxic and dangerous for the environment. Concentrated potassium hydroxide is corrosive (see safety data sheet). Do not open the housing or penetrate the permeable membrane. Do not touch a damaged sensor without protective gloves. In the case of leakage avoid contact with eyes. The sensor is not suited for use in a magnetic resonance imaging (MRI) environment. Cleaning/ Disinfection: The sensor membrane and the printed circuit board should not come in contact with disinfectant or cleaning agent. The other parts of the sensor can be disinfected by disinfectant wipes or with a surface disinfection agent. Follow the instructions of the producer of the disinfection material. Before insertion into the device check the sensor for mechanical damages and for humidity or crystallization of salts on the housing. Do not use a damaged sensor or a sensor with crystallization of salts outside.	

Safety advice on product:	Not available	**On R-17 Med sensor from 2009** Pouch: The product contains a chemical known to the state of California to cause cancer or reproductive harm. On Label: Contains caustic. Causes severe burns. Maybe fatal if swallowed.	 The sensor contains caustic liquid. In case of leakage avoid contact with eyes and skin.	
Labelling, type label:	Not available	See below	See below	
...				

Label Envitec



Label Teledyne

Bewertung / Appraisal:

☐ Die Produktunterlagen, Sicherheitshinweise und Kennzeichnungen am Produkt sind vergleichbar und gewährleisten die sichere Verwendung.
The accompanying documents, safety advice and product labels are comparable and ensure a safe use.

☒ Folgende Abweichungen/Ergänzungen haben keinen Einfluss auf die sichere Verwendung:
The following deviations/additions have no adverse influence on the safe use:

- The safety indications for MOX 9 sensors are mainly applicable for industrial applications. Solvents and soldering and spanners are not expected in hospitals. The other advice is comparable.

4.3 Vergleiche der Technischen Daten / Spezifikationen / Comparison of Technical Data / Specifications

Product, performance data:	Equivalent product I	Equivalent product II	Product of clinical evaluation	Comments
Measuring range:	0-100% 0-1500 mBar O_2	0-100%	0-100% (ppO_2 0 - 1250 mBar O_2)	
Measuring accuracy:	Not specified	Within ±2% @ 60% O_2; ±3% @ 100% O_2 at constant temperature and pressure when calibrated in air	Meets ISO 80601-2-55 requirements	
Output	10-13 mV in 210 mBar O_2	10-17 mV in air, sea level at 25° C	13-16 mV in ambient air	
Response time (T_{90})	15 s (air to 100% O_2)	10 s	12 s	
Offset	<200µV	Less than 0.5% of oxygen equivalent in zero gas after 60 s	150µA	
Temperature compensation	< 2% O_2 equivalent (0-40°C)	5% of full scale over the operating temperature range, worst case tracking error (within the first hour after a maximum temperature step) is 7.5% full scale	Between +25° C and +40° C: 3% relative error between 0° C and +50° C: 8% relative error	
Material, design:				
Standards and classifications:	ISO 60601-2-55	Not specified	ISO 60601-2-55	
EMC:	Not applicable	Not applicable	Not applicable	
Environmental conditions: Operation	• -20°C to 50°C • 0.5 to 2.0 Bar • 0-99% RH non-condensing	• 0°C to 40°C • 0-99% RH non-condensing	• 0°C to 50°C • 0.6 to 2.0 Bar • 0-99% RH non-condensing	
Environmental conditions: Storage, transport	-10°C to 40°C (short excursions to 50°C allowed)	0°C to 50°C	-20°C to 50°C (recommended 5°C to 15°C)	
Warranty	13 months from date of dispatch		15 months	
Expected Cell Live	0.9 x 106% O2 hours at 20° C 0.6 x 106% O2 hours at 40° C	24 months in air at 25°C and 50% R.H.	>1.000 000 % vol. oxygen hours	

Bewertung / Appraisal:

☐ Die Gleichwertigkeit mit allen Leistungsdaten der Vergleichsprodukte konnte nachgewiesen werden. / *All technical data of the products compared are equivalent.*

☒ Folgende Abweichungen/Ergänzungen haben keinen Einfluss auf die sichere Verwendung: / *The following deviations/additions have no adverse influence on the safe use:*

- Different outputs in air are tolerated by the target analyzers and are not important for safety reasons. The analyzer checks the signal in air and rejects sensors with signals out of the target range.
-

5 Bewertung der Marktbeobachtungsdaten /Appraisal of data from market surveillance

Medical O2 sensors are produced and sold for 20 years by ENVITEC. All complaints of that product group from 2005 until May 2015 were reviewed (since that time our complaints are recorded in a database). No cases were identified that resulted in a hazardous situation or could have resulted in a hazardous situation. Due to the long-term market experience without hazardous situations, the residual risk is evaluated as acceptable.

6 Abschließende Bewertung / Final Evaluation

Nach oben aufgeführter klinischer Bewertung kann die Übereinstimmung des Produktes mit den Grundlegenden Anforderungen der Richtlinie 93/42/EWG festgestellt werden. Das Produkt ist für die oben aufgeführte Anwendung und die beschriebene Zweckbestimmung als ***sicher im Sinne der Richtlinie*** zu bezeichnen. Die mit dem Produkt verbundenen (Rest-)Risiken sind vertretbar gering gegenüber dem klinischen Nutzen.

*Based on the above clinical evaluation the Product complies with the Essential Requirements of the European Directive 93/42/EEC. The Product **is to be considered safe in the scope of the Directive** for the above application and the intended use as described. The residual risks attributed to the Product are acceptably low compared with the Product's clinical benefit.*

Für die oben aufgeführte Bewertung zeichnet verantwortlich / *The above appraisal has been made by:*

Wismar, 2015-10-09

.....
R&D Manager / Quality Manager

Appendices: