

CERTIFICATE OF COMPLIANCE



MAK Certification
hereby declares that the product

pipe coupling, type BioConnect®

from

NEUMO GmbH & Co. KG, Germany

has been evaluated for compliance with the Hygienic Equipment Design Criteria
of the EHEDG, Document No. 8, by:

MAK (Lehrstuhl für Maschinen- u. Apparatekunde der TUM) at Weihenstephan, Germany
and meets the criteria of this document as demonstrated by:

Evaluation Report No. 76.2/23.12.2003

Signed Jürgen Hoffmann
Evaluation Officer

Date 15. May 2006

Signed Dr. Gerhard Haumer
Head of Department

Date 15. May 2006

Certificate No. 11/2006



MAK, Am Forum 2, 85350 Freising-Weihenstephan, Germany
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CONTRACT TO USE THE EHEDG CERTIFICATION LOGO FOR EQUIPMENT

A Contract entered into this **15th of May 2006** between EHEDG, an organization existing under Netherlands law, with its Secretariat at Avenue Grand Champ, 148, 1150 Brussels, Belgium, herein after called "EHEDG" and

NEUMO GmbH & Co. KG, Henry-Ehrenberg-Platz, D-75438 Knittlingen, Germany, herein after called "Company".

1. Certified product(s) are any equipment, component, system, material or service for which EHEDG has specifically authorized the use of the EHEDG Certification Logo. The EHEDG Certification Logo is a registered mark. All existing rights in connection with or future rights through the use of the logo are exclusively reserved to the EHEDG.
2. EHEDG or an EHEDG Authorized Organization (Appendix 1A) has determined that the products identified in Article 9 of this Contract comply with the requirements of the applicable criteria and certification classification under Appendix 1B (EHEDG Certification Type) of this Contract.
3. Upon execution of this Contract and payment of any outstanding fees, EHEDG authorizes the Company to use the EHEDG Certification Logo on the products identified in Article 9, subject to the conditions described in Appendix 2 (Conditions for Use of the EHEDG Certification Logo) of this Contract for a period of one year. The period may be extended annually by providing documentation, which shows that the products certified still fully meets the provisions of this Contract and payment of an annual prolongation fee.
4. The Company undertakes to place the Logo only on those products, which have been certified in compliance with this Contract.
5. It is understood and agreed that a Logo on a product and its Certification are invalid if the product has been significantly altered or has been represented as being Certified for any purpose or end use other than that Certified by EHEDG. EHEDG assumes no liability for any claims arising from such alteration, misuse, or misrepresentation by the Company.
6. The Company assumes responsibility to inform EHEDG or an EHEDG Authorized Organization of any changes or modification in the design and manufacture of certified products which may affect its compliance with the EHEDG Criteria.
EHEDG or an EHEDG Authorized Organization will judge whether the changes or modifications render the current certification void.
The need of review of the modified product depends on the modification being carried out. Some modifications might be considered to be of such a nature that a review would not appear to be necessary. But nonetheless the company has to report all of the modifications, however small they may be and even though they do not apparently impact on the design.

7. EHEDG assumes no liability for any claims for damages of any kind occurring to any person or entity as a result of sale, resale, use or misuse of the Company's products, whether or not the products are certified.

The Company assumes full and complete responsibility for its use of the Logo or other representation that its products are certified. EHEDG assumes no liability for any claims arising from the Company's misuse of the Logo or misrepresentation of the Certification status of its products.

8. This Contract is concluded for an indefinite period of time. The Company undertakes to declare in writing the latest by 31st December of the following year that no modifications were made on the certified product, or parts thereof. If modifications have been made on the certified product, the Company is to notify EHEDG or an EHEDG Authorized Organization thereof who determines whether the certified product needs review or not.

The Contract may be terminated at three months' notice to the end of the year. The notice must be given in writing per registered letter. The right to terminate the Contract for cause remains unaffected. Good cause is especially given, if the licence fees were not paid or modifications have been carried out on the certified product without prior notification.

This Contract will be terminated when replaced by a mutually agreed new contract or contract revision provided by EHEDG or in case of abuse of the Logo as mentioned under 14, below.

9. The EHEDG Logo may be used on or in connection with the following products:

- **pipe coupling, type BioConnect®**

as shown on the drawings or copies of drawings with original (NOT copied) EHEDG stamp, dated and signed by EHEDG, provided that the equipment - if applicable - has means for use and/or mounting such that compliance with the EHEDG Criteria is not adversely affected.
(If needed: additional remarks or conditions, based on the Evaluation Report.)

10. EHEDG or the EHEDG Authorized Organization will keep all documents and other evidence of the Company's product on file. The Secretariat of EHEDG will keep records of products that have been certified.

EHEDG or the EHEDG Authorized Organization undertakes to treat all documents received from the Company as confidential.

11. Upon request, a Certificate will be provided bearing the EHEDG Corporate Logo and optionally the name and/or logo of the EHEDG Authorized Organization, with the following statements:

- "Certificate of Compliance with the Hygienic Design Criteria of EHEDG".
- **"MAK hereby declares that the product *pipe coupling, type BioConnect®* from *NEUMO GmbH & Co. KG, Henry-Ehrenberg-Platz, D-75438 Knittlingen, Germany*, has been evaluated by *Lehrstuhl für Maschinen- und Apparatekunde, TU München Weihenstephan (MAK)* for compliance with the Hygienic Design Criteria of EHEDG. The results justify the use of the EHEDG Certification Logo Type (*type identification as shown on Appendix 3 of this Contract*)."**

The Certificate will be signed and dated.

12. Abuse of the Logo (i.e. its use under conditions conflicting with this Contract,) may result in any or all of the following sanctions:
- a) a request to immediately take corrective actions;
 - b) termination of the Contract;
 - c) a request to the appropriate court for indemnities and damages to the maximum amount of Euro 10.000,- per case.

Examples of Abuse:

The Company uses the EHEDG certification logo on products, drawings, brochures or other documents which have not been certified.

The Company uses the EHEDG certification logo as general information on documents, advertising and any type of publicity.

The Company uses the EHEDG certification logo on modified products, drawings, brochures or other documents without prior notification to EHEDG.

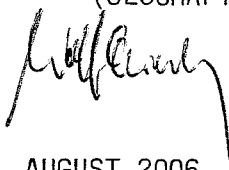
The Company uses the EHEDG certification logo on certified products, drawings, brochures or other documents using another name and/or designation without prior notification to EHEDG.

13. Disputes between Parties in connection with or arising out of the contract, which cannot be resolved by arrangement between parties, shall be finally settled by arbitration in accordance with the rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbiters appointed in accordance with those rules. The place of arbitration shall be Den Haag (The Hague).
14. This Contract and referenced documents constitute the entire agreement between Parties and supersede all previous communications, representations or agreements between Parties with respect to the Certified products. No modification will be binding upon either party unless it is made in writing and is signed by duly authorized representatives of both Parties.
15. This Contract will be subject to Netherlands law.

For **NEUMO GmbH & Co. KG**

Name and Title: WOLF EHRENBURG
(GESCHÄFTSFÜHRER)

Signature:

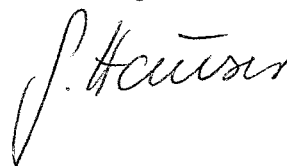


Date: 10. AUGUST 2006

For EHEDG: **Lehrstuhl für Maschinen- u. Apparatekunde, TU München Weihenstephan**

Name and Title: Dr.-Ing. G. Hauser

Signature:



Date: 15. May 2006

This Contract is not complete without the following documents:

Appendix 1A - EHEDG Authorized Certification Organisations

Appendix 1B - EHEDG Certification Type EL

Appendix 2 - Conditions for Use of the EHEDG Certification Logo

Appendix 3 - EHEDG Certification - Equipment Evaluation Form

Drawings, stamped, signed and dated by or on behalf of EHEDG, as specified under article 10 of this Contract.

Appendix 1A

EHEDG AUTHORIZED CERTIFICATION ORGANISATIONS

CCFRA Technology Ltd

Mr A Timperley
Chipping Campden
Glos, GL55 6LD
U.K.
Tel. +44 1386 842067
Fax +44 1386 842100

Danish Technological Institute

Mr J Kold
Holbergsvej 10
DK-6000 Kolding
Denmark
Tel. +45 7220 1920
Fax +45 7552 9989

TNO Certification B.V.

Ir D.L.R. Bakker
P.O. Box 541
NL-7300 AM Apeldoorn
Netherlands
Tel. +31 55 549 34 68
Fax +31 55 549 32 88

TU München

Lehrstuhl für Maschinen- und Apparatekunde
Mr J Hofmann
Am Forum 2
D-85350 Freising-Weihenstephan
Germany
Tel. +49 8161 71 4231
Fax +49 8161 71 4242

Appendix 1B

EHEDG CERTIFICATION TYPE EL

EQUIPMENT INTENDED FOR CLEANING WITH LIQUIDS

Equipment intended for cleaning with liquids may be ***EHEDG Certified*** if it complies with the Hygienic Design Criteria (HDC) of the EHEDG, as published in EHEDG Document no. 8.

EL Certification

EL Certification applies to equipment of which inspection, including inspection of any evidence* provided, by an EHEDG authorised organization has shown that it either fully complies with the HDC, or that ***for functional reasons, which are unavoidable***, does not fully comply with the HDC, but additional evidence* has been provided that specified measures compensate for the lack of compliance. The logo may then be used under the provisions that these specific measures are clearly mentioned where and when the logo is used and they are clearly described in any technical description of the equipment as well as in any operating instructions to be provided by the equipment supplier.

Examples

- A pipe bend made of stainless steel type AISI 316, of which the product contact surface is crevice free and has a surface roughness $R_a < 0.8\mu\text{m}$.
- A diaphragm valve free from crevices and also otherwise complying with the HDC, of which testing removed doubts about its cleanability.
- A tank with a mechanical shaft seal and a slide bearing has two unavoidable functional crevices. All other HDC are met. Evidence showed that rotating the shaft at a specified speed, with the relevant parts submerged in the cleaning solution for a specified time, compensates the lack of compliance with the HDC.

* *Evidence may typically consist of reports of cleanability tests, but also include results of the measurement of surface roughness, radiuses of corners, etc.*

Other products and services to be defined when available.

Appendix 2

CONDITIONS FOR USE OF THE EHEDG CERTIFICATION LOGO

EQUIPMENT INTENDED FOR CLEANING WITH LIQUIDS

EHEDG Certification of equipment intended for cleaning with liquids is possible if it complies with EHEDG Hygienic Design Criteria (HDC). The decision whether or not to grant certification rests with the EHEDG and must be based on an evaluation report (Appendix 3: EHEDG Certification - Equipment Evaluation Form). The EHEDG may delegate this responsibility to organizations that for this purpose have been authorized by the EHEDG. Hereinafter, "EHEDG" shall mean the EHEDG organization or an EHEDG Authorized Organization.

1. Eligibility

An Applicant with Products which comply with the HDC published by EHEDG.

2. Application for EHEDG Certification

An application shall be submitted by the Applicant for each Product together with the appropriate fee.

3. Contract for EHEDG Certification

Upon obtaining evidence of compliance (see Appendix 1B: EHEDG Certification Type), a contract shall be executed by the Company and EHEDG or an EHEDG Authorized Organization (see Appendix 1A). The contract shall detail the Product for which Certification is provided. The Certification Logo will be dated (month and year) and will last for life unless the equipment, or any part thereof, is modified, in accordance with clauses 3 and 6 of the Contract.

4. Use of the Logo and responsibility of Applicant

- 4.1 The Applicant shall represent as Certified, by use of the Logo or otherwise, only Products described in the Contract.
- 4.2 The language allowed is either "certified by EHEDG" or "EHEDG Certified". Correct literal translations are also allowed.
- 4.3 The Logo may be printed in black or in two colours. If printed in two colours, "EHEDG" must be in red no. PMS 032 and all other text in blue no. PMS 072 (see 13, below).
- 4.4 The Logo must be used in combination with either "TYPE EL" and with the date (month in text and year in four digits) of Certification. Both must be produced below the logo in the way shown in under 13. The text "TYPE EL" must be at least 1/10 times the size of the logo and the date must be at least 1/20 times the size of the logo, but both must never be less 2 mm in height. The font must be ARIAL Rounded MT Bold or ARIAL (Western) Bold or similar and equally clear.
- 4.5 If the logo is applied directly on to the Product, this may be done without using colours. If colours are used, the colours mentioned under 4.3 must be used, as indicated. It must be ascertained that the use of the Logo on Products does not adversely affect either hygiene or food safety. Dimensional requirements are as specified under 4.4.
- 4.5 The Logo may not be cropped in any way.
- 4.6 The Logo may be used in combination with other logos or marks.
If used in combination with other logos, it does not automatically mean that the EHEDG is linked to those organisations in one way or the other.

5. Written Authorization for Certification and Use of the Logo

The EHEDG Logo is a registered Mark. No Company or person shall apply or use the Logo in connection with a Product, or represent in any way that the Product is EHEDG Certified, until receipt of written authorization from EHEDG. EHEDG may pursue legal recourse if the Logo is misused.

6. Transfer of Authorization for Certification and Use of the Logo

Upon request and with documentation of continued compliance, EHEDG may transfer authorization for continued Certification of specific Products to another Company for the purpose of a name change, change of ownership, or change of a production location. An administration fee will be charged.

7. EHEDG Acknowledgement of Certified Products

Certified Products may bear the Logo or be otherwise represented as Certified.

8. Trade Designations

A Company shall not use the letter combination "EHEDG" in its trade designation (e.g. name, model number, or other identification assigned by the Company) for a Certified or non-Certified Product.

A Company shall not have a trade designation for a Certified Product that directly or indirectly states or implies an end use application for which the Product is not Certified.

9. Product modification

Any modification of the product, which has been certified renders the Certification void for the modified products. If Certification of the modified product is desired, a new application must be submitted. If the modification proves to be relatively insignificant, the fee may be reduced or waived at the discretion of EHEDG.

10. Implementation of Revisions to Referenced EHEDG Guideline(s)

Upon adoption of a revision to any referenced EHEDG Guideline(s), mentioned in the Contract, the Company shall be encouraged to implement all changes in requirements in its Certified Products.

11. Certification of Distributors

A Company distributing a Certified Product with a trade designation other than that of the original manufacturer may apply for an extra EHEDG Certification at a reduced fee.

12. Private Labelling of Certified Products

If a Company has the intention to label Certified Products with another name and/or designation the Company shall prior to any changes notify the EHEDG thereof it in writing. On written consent of the EHEDG, the Company may proceed as intended.

13. Example of the EHEDG Certification Logo



Appendix 3

EHEDG CERTIFICATION - EQUIPMENT EVALUATION FORM
OFFICIAL ENGLISH VERSION
EQUIPMENT INTENDED FOR CLEANING WITH LIQUID, TYPE EL

Equipment:

Name: NEUMO GmbH & Co. KG

Type no.: BioConnect®

Other essential identification: pipe connection

Date: 15. May 2006

Number: 11/2006

Evaluated by:

Name: Jürgen Hofmann

EHEDG or EHEDG Authorized Organization: MAK


Approved by:

Name: Andrew Timperley

EHEDG or EHEDG Authorized Organization: CCFRA Technology Ltd, UK

1. Results of inspection for compliance with the EHEDG Hygienic Design Criteria. Conclusion : The equipment complies with the criteria. The use of the EHEDG Certification Type EL logo is justified :	<div style="display: flex; justify-content: space-between;"><div>YES</div><div><input type="checkbox"/></div></div> <div style="display: flex; justify-content: space-between;"><div>MAYBE</div><div><input checked="" type="checkbox"/></div></div> <div style="display: flex; justify-content: space-between;"><div>NO</div><div><input type="checkbox"/></div></div>
2. Evidence of compliance with the EHEDG Hygienic Design Criteria provided and convincing. Conclusion : The equipment complies with the criteria. The use of the EHEDG Certification Type EL logo is justified :	<div style="display: flex; justify-content: space-between;"><div>YES</div><div><input checked="" type="checkbox"/></div></div> <div style="display: flex; justify-content: space-between;"><div>NO</div><div><input type="checkbox"/></div></div>
3. Only unavoidable reasons for non-compliance present. Evidence for compensation provided and convincing for Certification.. Conclusion : The equipment complies with the criteria where possible. The use of the EHEDG Certification Type EL logo is justified :	<div style="display: flex; justify-content: space-between;"><div>YES</div><div><input type="checkbox"/></div></div> <div style="display: flex; justify-content: space-between;"><div>NO</div><div><input type="checkbox"/></div></div>

Signature :



Date : 15 May 2006

The original of this form will be kept together by the EHEDG or the EHEDG Authorized Organisation with the application, the inspection report, the evidence provided and any other relevant documentation, as listed on the back.

Type EL Certification : Yes~~NO~~*Cross out as appropriate.*

EHEDG Evaluation Report
no. 76.2/23.12.2003

OFFICIAL ENGLISH VERSION

pipe coupling, type BioConnect®

NEUMO GmbH & Co. KG, Germany

The evaluation is based on a EHEDG in-line cleanability test report of **MAK (Lehrstuhl für Maschinen- und Apparatetechnik, Technische Universität München Weihenstephan, Germany)**, discussion with Dr.-Ing. Gerhard Hauser and Dipl.-Ing. Jürgen Hofmann, who was responsible for the tests.

Evaluation of the hygienic design criteria of EHEDG doc. 8

Materials of construction

All used materials fulfil the specific requirements. They are corrosion resistant, non-toxic, mechanically stable, and their surface finish is not adversely affected under the conditions of intended use. The pipe connection is made of stainless steel alloy 1.4435 / 316L, which has a good corrosion resistance. The used gasket (O-ring) is EPDM in line with FDA CFR.

Hygienic Design and construction


All product contact surfaces are free of imperfections. The design has no steps and sharp corners. The surface roughness of the product contact areas of the pipe connection is polished and has a mean roughness of $R_a = 0.3 \mu\text{m}$. Both flanges are centred and have an axial stop according EHEDG requirements. The pipe connection must be welded in an hygienic and cleanable way to the pipeline.

The sealing is right at the front on the product side. The O-ring has a defined compression and the expansion area to the front.

Result

The conclusion is that the **pipe connection, type BioConnect®** complies with all the EHEDG Hygienic Design Criteria (doc. 8 and 10).

The in-place cleanability test method has proven that this pipe connection, type BioConnect® is easy to clean. The cleanability was comparable to the reference pipe.


Dipl.-Ing. J. Hofmann
15. May 2006

Drawing of the pipe connection, type BioConnect®

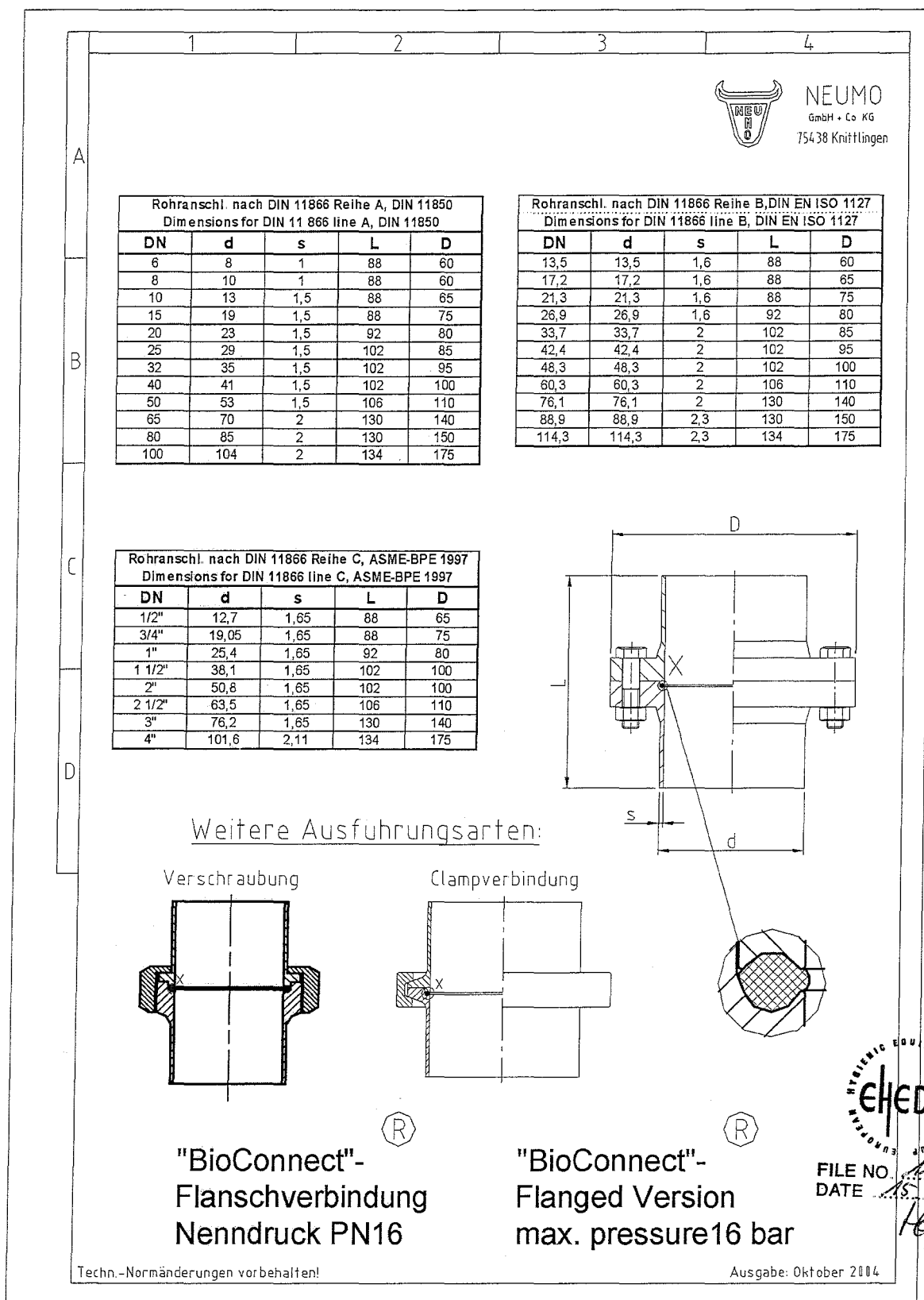


Fig.: pipe connection, type BioConnect®