



## **DECLARATION OF CONFORMITY**

The manufacturer **MEDOP**, head office in Zabala 16 Street - 48003 BILBAO (Vizcaya), declares that the following product unader Class I meet the provisions of Council Directive 93/45/EEC, concerning medical devices and Category 3 meet Directive 89/686/EEC, concerning PPE which apply to them:

Powdered and Powder free Latex Gloves  
Powdered and Powder free Nitrile Gloves

The following standards were used to prove the products conformity with essential requierements of above directive: EN 455, EN 374, EN 420 and Plastic Material and Articles in contact with Food Commission Regulation (EU) No 2016/1416.

All the products are identical to the PPE which is the subject of **EC certificates of conformity numbers 03413389, 03413390 and 034/2016/0218**, issued by CEBTEXBEK, as Control Notified Body number 5876.

Bilbao, on 27<sup>th</sup> of March 2017

Inés Gómez-Rubiera

**Dr. Ralph Derra**Öffentlich bestellter und vereidigter Sachverständiger für  
Verpackungsmaterialien, Boden- und Luftanalysen;  
Sachverständiger in der Wasseranalytik

29 March 2017

Dr. Dr/Ni-so

**UNBEDENKLICHKEITSERKLÄRUNG  
CERTIFICATE OF COMPLIANCE  
CERTIFICAT DE CONFORMITE**eingetragen  
registered no.  
registré

44473 U 17

für  
for  
pourMEDOP  
Bruno Mauricio Zabala, 16-7°  
48003 Bilbao (Vizcaya)  
SpainProdukt  
Product  
Produit

MEDOP Nitrile Gloves

The unpowdered nitrile gloves distributed by the company mentioned above are used in the food industry during the handling and preparation of food.

They were examined by us according to the

Methoden zur Untersuchung von Kunststoffen, soweit sie als Bedarfsgegenstände im Sinne des Lebensmittel- und Bedarfsgegenstandegesetzes verwendet werden, einschließlich der 62. Mitteilung des BfR zur Untersuchung von Hochpolymeren, Bundesgesundheitsblatt 50, 524 (2007), Stand vom April 2007,

(Methods for testing plastics as far as they are used as consumer goods as defined by the Foodstuffs and Consumer Goods Act, including the 62<sup>nd</sup> memorandum of the BfR on the examination of high polymers, Bundesgesundheitsblatt 50, 524 (2007), state of April 2007),

for the composition as well as for the release of substances which might endanger health and to the

“Methoden zur Untersuchung von Bedarfsgegenständen, Grundregeln für die Ermittlung der Migration in Prüflebensmittel“, entsprechend der Vorschrift Nr. 80.30, 1 - 3 (EG) in der Amtlichen Sammlung von Untersuchungsverfahren nach § 64 des Lebensmittel- und Futtermittelgesetzbuchs - LFGB, Stand vom April 2008,

(“Methods for the examination of consumer goods, basic rules for the determination of the migration into food simulants“, according to the standard no. 80.30, 1 - 3 (EC) within the Official Collection of Testing Methods according to § 64 of the Foodstuffs and Animal Feed Code - LFGB, state of April 2008),

as well as to the

Series of standards EN 1186, EN 13130 and CEN/TS 14234 “Materials and Articles in Contact with Foodstuffs – Plastics“, current state,

for the migration behaviour.

The gloves are in compliance with the rules of the

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Official Journal of the European Union L 338/4 of 13.11.2004, modified by app. no. 5.17 of the regulation (EC) No 596/2009 of 18 June 2009, Official Journal of the European Union L 188 of 18 July 2009, article 3,

as well as of the

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Lebensmittel- und Futtermittelgesetzbuch - LFGB) in der Fassung der Bekanntmachung vom 3. Juni 2013 (BGBl. I S. 1426), zuletzt geändert durch Artikel 10 des Gesetzes vom 10. März 2017 (BGBl. I S. 420), §§ 30 und 31,

(Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code - LFGB) in the version of the notification of 3 June 2013 (BGBl. p. 1426), last amendment by article 10 of the act of 10 March 2017 (BGBl. I p. 420), §§ 30 and 31).

They meet the demands of the

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Official Journal of the European Union L 12/1 of 15 January 2011, last amendment by Commission Regulation (EU) No 2016/1416 of 24 August 2016, Official Journal of the European Union L 230/22 of 25 August 2016,

with regard to the migration behaviour and are approved according to the

Deutsche Empfehlung XXI zur gesundheitlichen Beurteilung von Materialien und Gegenständen für den Lebensmittelkontakt im Rahmen des Lebensmittel- und Futtermittelgesetzbuches, 13. Mitteilung, Bundesgesundheitsblatt 5, 403 (1962), einschließlich 220. Mitteilung, Bundesgesundheitsblatt 59, 1365-1368 (2016), Stand vom 01.07.2016,

(German Recommendation XXI for the health-related evaluation of materials and objects for the contact with foodstuffs in the frame of the Foodstuffs and Animal Feed Code, 13th memorandum, Bundesgesundheitsblatt 5, 403 (1962), including the 220<sup>th</sup> memorandum, Bundesgesundheitsblatt 59, 1365-1368 (2016), state of 1 July 2016).

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Thus, the MEDOP Nitrile Gloves according to the sample material submitted may be used safely during the preparation and handling of food in the food industry and may stand in direct contact with all types of food for a short period of time. The ratio of the food contact surface of the gloves and the mass of the food shall not exceed 8.4 dm<sup>2</sup> per 5 kg food.

This certificate of compliance has a validity until 2 May 2018 and consists of 4 pages.

Certification decision



staatlich anerkannter Sachverständiger  
zur Untersuchung der Gegenproben von  
Verpackungsmitteln aus Papier, Pappe,  
Kunststoffen, Glas, Weißblech und  
sonstigen Metallverpackungen auf ihre  
Lebensmittelrechtliche Unbedenklichkeit

(Behrendt)  
Officially certified  
and authorized food  
chemist



**Staatlich anerkannter Sachverständiger zur Untersuchung der Gegenproben von Verpackungsmitteln aus Papier, Pappe, Kunststoffen, Glas, Weißblech und sonstigen Metallverpackungen auf ihre lebensmittelrechtliche Unbedenklichkeit**

Dr. Ralph Derra

Authorized expert for the analyses of packaging materials, attested by the Aschaffenburg Chamber of Industry and Commerce.

Expert autorisé pour l'analyse des matériaux d'emballage, assermenté par la Chambre d'Industrie et de Commerce d'Aschaffenburg.

State registered expert for the analysis of contrasting samples of packaging materials of paper, board, plastics, glass, tin plate and other metallic packaging materials as to their suitability for use with foodstuffs.

Expert public pour l'étude du contrôle des contre-échantillons d'emballages de papier, cartons, plastiques, verre, fer-blanc et d'autres emballages métalliques concernant leur conformité alimentaire.



Dr. Ralph Derra

Authorized expert for the analyses of soil and air, attested by the Aschaffenburg Chamber of Industry and Commerce.

Expert autorisé pour l'analyse du sol et de l'air, assermenté par la Chambre d'Industrie et de Commerce d'Aschaffenburg.

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Die Rücklagen des untersuchten Materials werden bei der Gutachterstelle verwahrt.  
Dieses Dokument ist eine Übersetzung einer deutschen Originalversion. In Streitfällen ist das Originaldokument die rechtlich bindende Version.  
A file sample of the tested material is kept at the expert's office.  
This document is a translation of an original in German. In case of dispute, the original document should be taken as authoritative.



In application of the directive 89/686/EEG of 21 December 1989 concerning the harmonisation of the Member States legislation relative to personal protective equipment, Centexbel Notified body 0493 authorised by decree AV/OA235/ST dated 94-05-25 of the Ministry of Employment and Labour has issued

## CE TYPE EXAMINATION CERTIFICATE

**Nr. 034/2016/0218**

**This CE Type examination certificate is valid until 08 Mar 2021**

to: **Medop, Bilbao**

for: **MEDOP NITRILE GLOVES Guante Nitrilo Desechable**

The personal protective equipment above mentioned satisfies the applicable essential safety requirements of the Directive.

For the argumentation, the following standards are used:

EN 420+A1:2009            Protective gloves - General requirements and test methods  
EN 374-1:2003            Protective gloves against chemicals and micro-organisms - Part  
1: Terminology and performance requirements

This is PPE of category III, subject to regular checks in accordance with article 11 of the European PPE directive. In agreement with the manufacturer's choice audits shall be carried out to assess the quality control system (art.11B). The manufacturer must be able, on request, to present the audit report. A first audit shall be performed at the latest on 31 Dec 2017 and at least be repeated with intervals of one year.

This declaration applies to the equipment as submitted in the type testing and described in the manufacturer's technical file that is registered with number 5882\_9.

Issued by Centexbel, Notified Body 0493<sup>(\*)</sup>, in Ghent, on 08 Mar 2016

Inge De Witte  
Certification Manager

Attached: 1 Annex

<sup>\*)</sup>Recognized by decree AV/OA235/ST of 94-05-25 of the Ministry of Labor and Employment