

ISEGA

Forschungs- und Untersuchungs-
Gesellschaft mbH Aschaffenburg

Dr. Ralph Derra

Öffentlich bestellter und vereidigter Sachverständiger für
Verpackungsmaterialien, Boden- und Luftanalysen;
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4 February 2022

Dr. Dr/Be-pf

UNBEDENKLICHKEITSERKLÄRUNG
CERTIFICATE OF COMPLIANCE
CERTIFICAT DE CONFORMITE

eingetragen
registered no.
régiistré

56373 U 22

für
for
pour

OP papírna, s.r.o.
Olšany 18
78962 Olšany
Czech Republic

Produkt
Product
Produit

OP Medical Print

The product manufactured by the company mentioned above is a paper grade which is used as printed leaflet for medical and cosmetic products as well as for food packaging.

It was examined by us under consideration of the

BfR-„Methodensammlung zur Untersuchung von Papier, Karton und Pappe für den Lebensmittelkontakt“, aktueller Stand, in Verbindung mit dem BfR-Leitfaden "Untersuchung der Stoffübergänge von Bedarfsgegenständen aus Papier, Karton und Pappe" vom 26.02.2015,

(BfR-“Collection of methods for the examination of paper and board for food contact” of the, current state), in connection with the BfR guideline “Examination of the transfer of substances from consumer products made of paper and board”, as of 26.02.2015),

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and according to the demands of the

Code of Federal Regulations, Food and Drugs (FDA), 21 CFR Ch. I (1 April 2021 edition),
§ 176.170,

for the used raw materials, fabrication additives and special paper finishing agents as well as
for the release of substances which might endanger health.

Furthermore, the heavy metals contents were determined according to the

Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994,
on packaging and packaging waste, Official Journal of the European Communities L 365/10
of 31 December 1994, last amendment by the Directive (EU) 2018/852 of the European
Parliament and of the Council of 30 May 2018, Official Journal of the European Union
L 150/141 of 14 June 2018.

The paper grade is 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 Direc-
tives 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, 1. (a) and (b),

as well as of the

Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Lebensmittel- und Futter-
mittelgesetzbuch - LFGB) in der Fassung der Bekanntmachung vom 15. September 2021
(BGBl. I S. 4253), zuletzt geändert durch Artikel 7 des Gesetzes vom 27. September 2021
(BGBl. I S. 4530), §§ 30 und 31,

(Foodstuffs, Consumer Goods and Animal Feed Code (Foodstuffs and Animal Feed Code
- LFGB) in the version of the notification of 15 September 2021 (BGBl. I. p. 4253), last
amendment by article 7 of the law of 27 September 2021 (BGBl. I p. 4530), §§ 30 and 31),

and is approved according to the

BfR-Empfehlung XXXVI. Papiere, Kartons und Pappen für den Lebensmittelkontakt, neu-
gefasst durch 62. Mitteilung, Bundesgesundheitsblatt 14 (1971) 83, zuletzt geändert durch
223. Mitteilung, Bundesgesundheitsblatt 64 (2021) 764, Stand vom 01.04.2021,

(BfR Recommendation XXXVI. Paper and board for food contact, recasted by 62nd An-
nouncement, Bundesgesundheitsblatt 14 (1971) 83, last amended by 223rd Announcement,
Bundesgesundheitsblatt 64 (2021) 764, as of 1 April 2021).

Furthermore, the paper grade is in compliance with the

Code of Federal Regulations, Food and Drugs (FDA), 21 CFR Ch. I (1 April 2021 edition),
§§ 176.170 and 176.180.

Additionally, the paper grade is in compliance with the

Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994, on packaging and packaging waste, Official Journal of the European Communities L 365/10 of 31 December 1994, last amendment by the Directive (EU) 2018/852 of the European Parliament and of the Council of 30 May 2018, Official Journal of the European Union L 150/141 of 14 June 2018,

regarding the heavy metals contents.

Thus the paper grade **OP Medical Print** according to the sample material submitted may be used safely for food packaging. It may stand in direct contact with dry and fatty foodstuffs.

Besides that, it may also be used in the printing sector and as a printed leaflet for medical and cosmetic products as far as the paper grade mentioned above is concerned.

This certificate of compliance has a validity of 2 years and consists of 4 pages.

Certification decision



amtlich anerkannter Sachverständiger
für Untersuchung der Gegenproben von
Verpackungsmitteln aus Papier, Pappe
Kunststoffen, Glas, Weißblech und
sonstigen Metallverpackungen auf ihre
lebensmitteltechnische Unbedenklichkeit



(Behrendt)
Officially certified
and authorized food
chemist

The translation of the above stamps is given on page 4.
La traduction des estampilles est donnée en page 4.



Staatslich 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.

Die Rücklagen des untersuchten Materials werden bei der Gutachterstelle verwahrt.
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A file sample of the tested material is kept at the expert's office.
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