NATIONAL MEDICINES INSTITUTE

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PCA Polskie Centrum Akredytacji BADANIA
AB 774

Customer: InnoNIL Sp. z o.o.,
ul. Chełmska 30/34
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The current version supersedes Test report No.BR-0064-21 issued on 10.02.2021	Copy number 1	page 1 / 3
TEST REPORT : BR – 0064-21	Date of issue: 01 KWI. 2021	

Date of the sample arrival:	05.02.2021
Sample code: BR-	BR-0064-21
Order number:	InnoNIL 0264-20
Type of the test :	Research expertise
Aim of the test:	Cytotoxicity in vitro

SAMPLE DATA:

Name:	Medical face mask type IIR
Other:	-
Pharmaceutical form:	-
Strenth/dose:	-
Date of Sampling:	04.02.2021
Date of production:	-
Expiration date:	-
Batch numer/batch number:	224211220
Manufacturer:	TW Plast Sp. z o.o,, ul. Puławska 38, 05-500 Piaseczno
Quantity of sample received:	two face masks
Descripton packing:	the face mask made of a non-woven fabric, white and blue coloured, placed in a foil zip-lock bag.

TEST RESULTS:

No.	Parameter	Test method	Requirement	Result
1.	Cytotoxicity in vitro	agar diffusion acc. to PN-EN ISO 10993-5:2009	—	cytotoxicity grade –"0" interpretation – none reactivity final result –sample non cytotoxic

Notice:

1. **Cell line, justification of the choice and cell source:**
Mouse fibroblast cells NCTC clone 929 recommended by PN-EN ISO 10993-5:2009; ATCC.

2. **Medium, serum, antibiotics:**
MEM Biowest, nr serii MS00JM; fetal bovine serum Biowest, nr serii S17448S1810; antibiotics solution Biowest, nr serii MS006W.

3. **Assay method and rationale:**

Agar diffusion, according to the order.

4. **Extraction procedure (if appropriate):**

Not applicable.

5. **Negative, positive and other controls:**

The controls used: intact cell culture, negative, positive.

6. **Cell response, other observations and any other relevant data necessary for the assessment of results:**

No detectable zone around or under specimen.

Additional data about the sample: sample appropriate for the test, at adequate size.

Tests results and interpretation apply exclusively to the tested samples

Start of the test: 08.02.2021 End of the test: 10.02.2021

Signature and stamp of the authorized person: Signature and stamp of the plant maneger:

Osoba upoważniona
dr n. biol. Irena Bubko

Kierownik Zakładu
Biochemii i Biofarmaceutyków
dr hab.n.farm. Beata M. Grabber-Bajda
profesor Instytutu

.....

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Analytical Report Nr. AR-21-YL-001750-01
Sample code Nr. 560-2021-00001762
Date 24/02/2021

ANALYTICAL REPORT

Client Information

Eurofins Polska Sp. z o.o.
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WARSZAWA POLAND

NataliaPapaja-Liczberska@eurofins.com
For the attention of Natalia Papaja-Liczberska

Sample Information

Order Code: EUAA70-00010699
Reception Date: 17-Feb-2021
Analysis Starting Date: 17-Feb-2021
Analysis Ending Date: 23-Feb-2021
Sample code Nr. 560-2021-00001762
Sample described as: Masks

Requirements and decision rule

Customer requirements: EN 14683:2019+AC:2019 TYPE IIR
Decision Rule: Shared risk - Simple acceptance. Probability of False Acceptance <50%

Information provided by the customer*

Client Reference: 720-2021-00027605
Sample Description:
Purchase Order Number:

Batch 224211220

Analytical Report Nr.	AR-21-YL-001750-01
Sample code Nr.	560-2021-00001762
Date	24/02/2021

SAMPLE PICTURE

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www.eurofins.com/tex

Analytical Report Nr. AR-21-YL-001750-01
Sample code Nr. 560-2021-00001762
Date 24/02/2021

CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
Breathability (Differential Pressure) EN 14683:2019+AC:2019 Annex C			
Mask	X		

Remark: Test has been performed as per application request

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Analytical Report Nr. AR-21-YL-001750-01
Sample code Nr. 560-2021-00001762
Date 24/02/2021

COMPONENT LIST:

COMPONENT ID	COMPONENT NAME	MATERIAL DESCRIPTION	COLOR	REMARKS
CUST 01	Mask	Mask	Blue	---

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Analytical Report Nr. AR-21-YL-001750-01
Sample code Nr. 560-2021-00001762
Date 24/02/2021

MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES

Analyses on:Mask

Breathability (Differential Pressure)

Analysis Ending Date: 23/02/2021

EN 14683:2019+AC:2019 Annex C

Differential pressure		30.2 Pa/cm²	(± 2.2) Pa/cm²	-	<60 Pa/cm² ✓ Pass

Complete test data reported at Annex.

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Analytical Report Nr. AR-21-YL-001750-01
Sample code Nr. 560-2021-00001762
Date 24/02/2021

Signed for and on behalf of Eurofins Textile Testing Spain:

Report electronically validated by

Axel Ferrando
Physical-Mechanical Lab Manager

EXPLANATORY NOTE

◆ Test not covered by ENAC accreditation scope
● Test is subcontracted within Eurofins group and is accredited
○ Test is subcontracted within Eurofins group and is not accredited
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The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor k = 2, which for a normal distribution provides a level of confidence of approximately 95%.
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METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

Test Method: EN 14683: 2019+AC: 2019 Annex C

Number of test specimens: 5

Number of test per specimen: 5

Sample area tested: Circular, diameter 2,5 cm

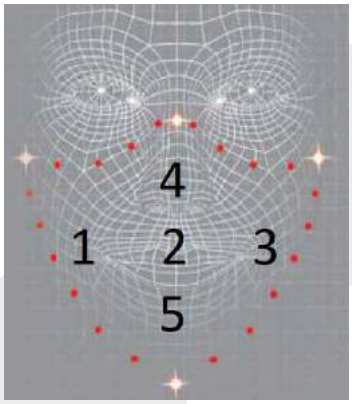
Tested area of the test sample: 4,9 cm^2

Flow rate during testing: 8±0,6 l/min

General location of measurement areas: Representative of the overall surface.

Conditioning: Tª between 16,7ºC and 26ºC. RH between 82,8% and 88% during at least 4 h.

Airflow direction during testing: From the inner layer to the outer layer.



Results

Specimen	Units (Pa)						ΔP (Pa/cm^2)
	Position 1	Position 2	Position 3	Position 4	Position 5	Mean value (Pa)	
1	122	136	143	140	136	135	27,6
2	166	139	129	139	141	143	29,1
3	141	146	151	137	153	146	29,7
4	167	163	189	174	196	178	36,3
5	161	123	135	148	123	138	28,2
						Mean Value	**30,2**
						Uncertainty	**± 2,2**

Observation:

For thick and rigid masks the test method may not be suitable as a proper seal cannot be maintained in the sample holder.

Operating requirements for surgical masks based on EN 14683: 2019+AC: 2019 standard

TEST	TYPE I	TYPE II	TYPE IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16
Microbial cleanliness (CFU/g)	≤ 30	≤ 30	≤ 30

Analytical Report Nr. AR-21-YL-002328-01
Sample code Nr. 560-2021-00002486
Date 15/03/2021

ANALYTICAL REPORT

Client Information

Eurofins Polska Sp. z o.o.
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WARSZAWA POLAND

NataliaPapaja-Liczberska@eurofins.com
For the attention of Natalia Papaja-Liczberska

Sample Information

Order Code:	EUAA70-00010999
Reception Date:	9-Mar-2021
Analysis Starting Date:	9-Mar-2021
Analysis Ending Date:	11-Mar-2021
Sample code Nr.	560-2021-00002486
Sample described as:	Masks

Requirements and decision rule

Customer requirements:	EN 14683:2019+AC:2019 TYPE IIR
Decision Rule:	Shared risk - Simple acceptance. Probability of False Acceptance <50%

Information provided by the customer*

Client Reference:	720-2021-00048987
Sample Description:	Maseczka medyczna wielowarstwowa typ IIR, 224211220, TW PLAST Sp. z o.o.
Purchase Order Number:	

Batch	224211220

Analytical Report Nr.	AR-21-YL-002328-01
Sample code Nr.	560-2021-00002486
Date	15/03/2021

SAMPLE PICTURE

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Analytical Report Nr. AR-21-YL-002328-01
Sample code Nr. 560-2021-00002486
Date 15/03/2021

CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
Resistance against penetration by synthetic blood **ISO 22609:2004**			
Mask	X		

Remark: Test has been performed as per application request

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Analytical Report Nr. AR-21-YL-002328-01
Sample code Nr. 560-2021-00002486
Date 15/03/2021

COMPONENT LIST:

COMPONENT ID	COMPONENT NAME	MATERIAL DESCRIPTION	COLOR	REMARKS
CUST 01	Mask	Mask	Blue	---

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Analytical Report Nr. AR-21-YL-002328-01
Sample code Nr. 560-2021-00002486
Date 15/03/2021

MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ		GUIDELINES

Analyses on:Mask

Resistance against penetration by synthetic blood

Analysis Ending Date: 11/03/2021

ISO 22609:2004

Number of specimens tested		32	-		
Number of specimens failed		0	-		
Number of specimens passed		32	-	≥29	✔ Pass

At least 29 of 32 specimens must pass tested at 16KPa

Complete test data reported at Annex.

AQL information according to ISO 22609:2004:
A single sampling plan providing an AQL of 4,0 % requires 32 test specimens.
An AQL of 4.0 % is met for a single sampling plan when 29 or more specimens show pass results.
AQL= Acceptable Quality Limit.

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Analytical Report Nr.	AR-21-YL-002328-01
Sample code Nr.	560-2021-00002486
Date	15/03/2021

Signed for and on behalf of Eurofins Textile Testing Spain:

Report electronically validated by

Maria Jesus Martinez Puig
Chemical Lab manager

EXPLANATORY NOTE

- ◆ Test not covered by ENAC accreditation scope
- ● Test is subcontracted within Eurofins group and is accredited
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DETERMINATION RESISTANCE AGAINST PENETRATION BY SYNTETIC BLOOD

Test Method: ISO 22609:2004; Targeting-plate test method

Number of test specimens: 32

Sample size: Circular, diameter 5,58 cm

Sample area tested: 24,5 cm^2

Pressure: 16 kPa (120,0 mm Hg)

Synthetic blood volume: 2 ml

Stream velocity of synthetic blood: 550±10 cm/s

Distance of the face mask target area surface from the tip of the cannula: 30,5 cm

Angle of the pneumatic valve with respect to the face mask target area: 90º

Technique used to enhance visual detection of synthetic blood: Hydrophilic cotton

Conditioning: At least 4 hours. Tª between 16,7ºC and 26ºC. RH between 82,8% and 88%

Environmental test conditions 18,5ºC; 88,5% Hr

Pre-treatment: None

Results		
Specimen	**Pass**	**Fail**
1	X	
2	X	
3	X	
4	X	
5	X	
6	X	
7	X	
8	X	
9	X	
10	X	
11	X	
12	X	
13	X	
14	X	
15	X	
16	X	
17	X	
18	X	
19	X	
20	X	
21	X	
22	X	
23	X	
24	X	
25	X	
26	X	
27	X	
28	X	
29	X	
30	X	
31	X	
32	X	

Conclusion	**PASS**

Operating requirements for surgical masks based on EN 14683: 2019+AC: 2019 standard

TEST	TYPE I	TYPE II	TYPE IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16
Microbial cleanliness (CFU/g)	≤ 30	≤ 30	≤ 30

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ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N° 1827 L

TEST REPORT	Refer to Analytical Report Number		
SPONSOR	Eurofins Eurofins Polska Sp. z o.o. ul. Wojska Polskiego 90A 82-200 Malbork POLAND		
FINAL CUSTOMER	TW PLAST Sp. zo.,o.		
TEST METHOD	Bacterial Filtration Efficiency (BFE) – EN 14683:2019+AC:2019 App B		
TEST ITEM - INFORMATION FROM THE SPONSOR			
PRODUCT NAME	720-2021-00027606 - Masecka medyczna typ IIR		
MATRIX OF THE PRODUCT	Face Mask		
BATCH	224211220	CODE	Not provided
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION			
MATERIAL ITEM ALIQUOT	N721AA0597-1		
PARCEL REGISTRATION N.	IP-N7-2021043-AAD	RECEIVING DATE	12 Feb 2021
ANALYSIS STARTING DATE	22 Feb 2021	**ANALYSIS ENDING DATE**	23 Feb 2021
EXPERIMENTAL CONDITIONS	Dimension of the test specimen: 175 mm x 95 mm Size of the area tested: 49 cm^2 Flow rate during testing: 28,3 l/min Inner side of the mask to the aerosol challenge.		
PHOTO OF THE TEST ITEM			
RESULTS			

	RESULT	UNIT
ALIQUOT 1	99,39	%
ALIQUOT 2	99,47	%
ALIQUOT 3	99,68	%
ALIQUOT 4	99,68	%
ALIQUOT 5	99,61	%

DETAILED RESULTS	See Addendum N. 1 *(1 page)*

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ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N° 1827 L

Addendum N.1

Started on: 22/02/2021

Batch: N721AA0597

Sample description: 720-2021-00027606 - Masecka medyczna typ IIR

Lot Number: 224211220

Negative Control Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Mean
Negative Control (CFU)	0	0	0	0	0	0	0

*number of colonies adjusted with positive-hole correction table

Positive Controls Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
Size of particle (µm)	7,00	4,70	3,30	2,10	1,10	0,65	
Positive Control N.1 (CFU)	133	260	1064	772	283	179	2691
Positive Control N.2 (CFU)	200	283	1109	874	292	160	2918

*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2805

Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,87
Positive Control N.2 (µm)	2,96
Mean (µm)	2,92

Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
N721AA0597-1 - Aliquot 1	0	0	0	2	6	9	17
N721AA0597-1 - Aliquot 2	0	0	0	2	2	11	15
N721AA0597-1 - Aliquot 3	0	0	0	2	3	4	9
N721AA0597-1 - Aliquot 4	0	0	0	1	3	5	9
N721AA0597-1 - Aliquot 5	0	0	0	2	3	6	11

*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
N721AA0597-1 - Aliquot 1	99,39
N721AA0597-1 - Aliquot 2	99,47
N721AA0597-1 - Aliquot 3	99,68
N721AA0597-1 - Aliquot 4	99,68
N721AA0597-1 - Aliquot 5	99,61

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Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Laboratory Manager
for Eurofins Cosmetic & Personal Care Italy Srl, on 24-Feb-2021 13:19:41 UTC+01:00

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LAB N° 1827 L

TEST REPORT	Refer to Analytical Report Number		
SPONSOR	Eurofins Eurofins Polska Sp. z o.o. ul. Wojska Polskiego 90A 82-200 Malbork POLAND		
FINAL CUSTOMER	TW PLAST Sp. z o.o.		
TEST METHOD	Microbial cleanliness (Bioburden) – EN 14683:2019/AC 2019 par. 5.2.5 + App D		
TEST ITEM - INFORMATION FROM THE SPONSOR			
PRODUCT NAME	720-2021-00027607 – Masecka medyczna typ IIR		
MATRIX OF THE PRODUCT	Face Mask		
BATCH	224211220	CODE	Not provided
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION			
MATERIAL ITEM ALIQUOT	N721AA0598-1		
PARCEL REGISTRATION N.	IP-N7-2021048-AAC	RECEIVING DATE	17 Feb 2021
ANALYSIS STARTING DATE	17 Feb 2021	**ANALYSIS ENDING DATE**	24 Feb 2021

RESULTS

TOTAL BIOBURDEN	SPECIFICATION	RESULT	UNIT
ALIQUOT 1	/	6.00	CFU/sample
	≤ 30	2.40	CFU/g
ALIQUOT 2	/	15.00	CFU/sample
	≤ 30	6.20	CFU/g
ALIQUOT 3	/	< 6.00	CFU/sample
	≤ 30	< 2.46	CFU/g
ALIQUOT 4	/	15.00	CFU/sample
	≤ 30	6.39	CFU/g
ALIQUOT 5	/	15.00	CFU/sample
	≤ 30	6.33	CFU/g

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Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Laboratory Manager
for Eurofins Cosmetic & Personal Care Italy Srl, on 24-Feb-2021 12:19:26 UTC+01:00

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T: (42) 631 46 53, F: (42) 631 46 57
e-mail: joanna.zelga@imp.lodz.pl

Customer (under Contract no. ZLB/45/2020):
TW PLAST Sp. z o.o.
05-500 Piaseczno, ul. Puławska 38
Tax Id. No. (NIP): 9372722562, Business Reg. No. (REGON): 383776873
National Court Register (KRS) No.: 0000792916, www.twplast.pl

SKIN IRRITATION TEST CERTIFICATE
STANDARD: PN-EN ISO 10993-10:2015-05

Medical device	Series number	Date of manufacture
Type I, II, IIR medical masks	105250920	25/09/2020

METHODOLOGY:
Standard: PN- EN ISO 10993-10:2015-02

DESIRED RESULT:
In dermal, single and repeated, closed exposure:
- the medical device does not irritate the skin locally;
- cumulative irritation index: 0.00;
- non-irritating medical device.

RESULT

☑ **NON-IRRITATING FOR THE SKIN** ☐ **IRRITATING FOR THE SKIN**

PERMITTED BY THE LOCAL ETHICAL COMMITTEE FOR EXPERIMENTS ON ANIMALS IN ŁÓDŹ, RESOLUTION NO. 29/ŁB 30/2016 OF 20 JUNE 2016 (ASSESSMENT OF LOCAL SKIN IRRITATION IN THE GMP QUALITY SYSTEM)

CONCLUSION:
Medical device - type I, II, IIR medical masks (series: 105250920, production date: 25/09/2020, manufacturer: TW Plast Sp. z o. o.):
- **should not pose a risk of local irritation to humans;**
- **the cumulative irritation index was 0.00;**
- **the test result meets the requirements of PN-EN ISO 10993-10:2015-02.**

Researchers:
Joanna Szulc, M.Sc. Biotechnology, Qualified Person *[illegible signature]*
Monika Borkowska, M.Sc. Eng. Biotechnology *[illegible signature]*
Monika Gorzkiewicz , M.Sc. Eng. Biotechnology *[illegible signature]*
Halina Szewczyk, Medical Analyst *[illegible signature]*
Marcin Lewandowski, Pharmacy Technician *[illegible signature]*
Marcin Połeć, Pharmacy Technician *[illegible signature]*

Qualified Person in Pharmacy
HEAD OF THE LABORATORY for
Research on Medicinal and Veterinary
Products in the GMP Quality System
[illegible signature]
Joanna Piasecka-Zelga, M.D. Ph.D.

Łódź, 2 November 2020
WHO Collaborating Center

I, Katarzyna Kaczmarczyk, Certified Translator and Interpreter of the English Language, entered onto the list of certified translators and interpreters kept by the Minister of Justice under no. TP/740/05, hereby approve conformity of the present translation with a scan of the original document in the Polish language.

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05-500 Piaseczno, ul. Puławska 38
Tax Id. No. (NIP): 9372722562, Business Reg. No. (REGON): 383776873
National Court Register (KRS) No.: 0000792916, www.twplast.pl

SENSITIZING EFFECT TEST CERTIFICATE
STANDARD: PN-EN ISO 10993-10:2015-05
MAXIMIZATION TEST (GMPT, MAGNUSSON AND KLIGMAN'S TEST)

Medical device	Series number	Date of manufacture
Type I, II, IIR medical masks	105250920	25/09/2020

METHODOLOGY:
Standard: PN-EN ISO 10993-10:2015-02 - maximization test (GMPT, Magnusson and Kligman's test)

DESIRED RESULT:
Skin reaction response ≤ 30% in the tested domestic guinea pig (Cavia porcellus) Imp:D-H
In accordance with the Regulation of the European Parliament and of the Council (EC) No 1272/2008 of 16 December 2008.

RESULT

☑ **DOES NOT CAUSE SKIN SENSITISATION** ☐ **CAUSES SKIN SENSITISATION**

PERMITTED BY THE LOCAL ETHICAL COMMITTEE FOR EXPERIMENTS ON ANIMALS IN ŁÓDŹ, RESOLUTION NO. 27/ŁB 28/2016 OF 20 JUNE 2016 (ASSESSMENT OF SKIN SENSITISATION IN THE GMP QUALITY SYSTEM)

CONCLUSION:
Medical device - type I, II, IIR medical masks (series: 105250920, production date: 25/09/2020, manufacturer: TW Plast Sp. z o. o.);
- **should not pose a risk of allergic reactions to humans;**
- **the test result meets the requirements of PN-EN ISO 10993-10:2015-02.**

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Łódź, 2 November 2020
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I, Katarzyna Kaczmarczyk, Certified Translator and Interpreter of the English Language, entered onto the list of certified translators and interpreters kept by the Minister of Justice under no. TP/740/05, hereby approve conformity of the present translation with a scan of the original document in the Polish language.