RoHS TEST REPORT

European Directive 2011/65/EU
Evaluation of RoHS Requirements for Electrical and Electronic Equipment

Test report No. ..... : RoHS-2012006

Receipt of date ..... : DEC 25, 2020

Issue of date ..... : DEC 28, 2020

Test of period ..... : DEC 25, 2020 ~ DEC 27, 2020

Applicant's name ..... : TKA Scientific Instruments Ltd.

Address ..... : 33/1 lit.B Gruzovoy proyezd, St. Petersburg 192289, RUSSIA

Manufacturer's name ..... : Same as applicant

Address ..... : Same as applicant

Product name ..... : Diagnostic device of human infection by Helicobacter pylory bacteria

Model(s) ..... : GastroTest

Test Specifications ..... : Directive 2011/65/EU

Test Standard(s) ..... : EN 50581:2012, EN 62321:2009

Test Result : The equipment which was evaluated has fulfilled with requirement of 2011/65/EU Directive for the materials : Pb, Cd, Hg, Cr(VI), PBBs and PBDEs

Also this publication represent for the evaluation results of the issued test item only - any type of EEE, i.e. full product, module assembly, component or material including RoHS test result.

The evaluation results means only the tested item is complied with RoHS requirement according to the evaluation procedures which is described in this publication.

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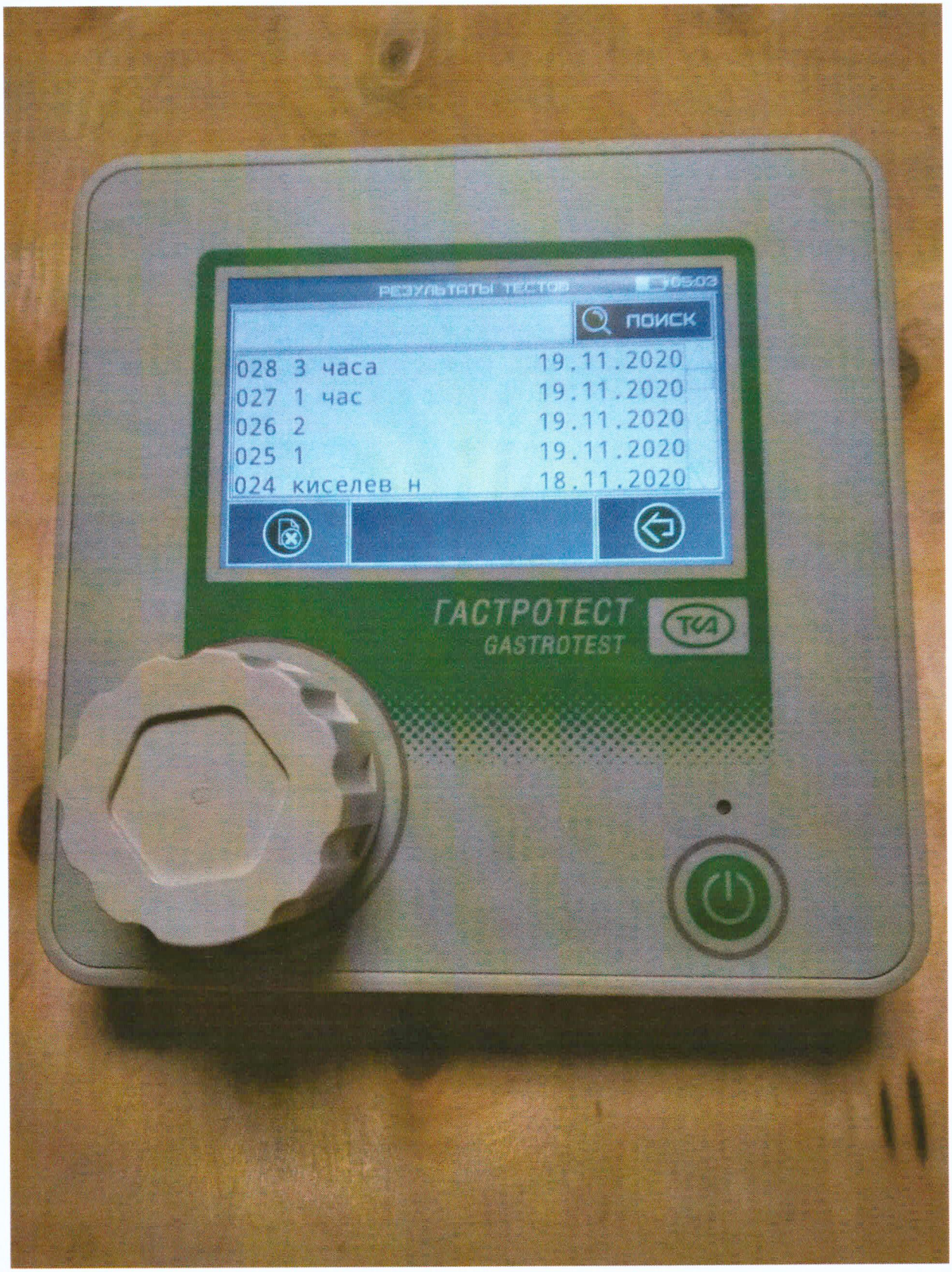
Clause	Requirement – Test	Result	Verdict
1	RoHS Compliance based on test reports		
1.1	Review of component's test reports according to BOM		P
1.1.1	Dose evaluated product is composed by components which is listed in BOM?	Checked	P
1.1.2	Dose each components is complied with the requirement of employed directive or manufacturer declared limits?	Checked	P
1.2	Review of verification test reports according to sampling		P
1.2.1	If it was performed the item 1.1, did sampling was performed in appropriate?	Refer to Appendix III	P
1.2.2	If it was not performed the item 1.1, did it was fully considered the materials of component and does it was performed the sampling which is enough to represent the characteristics of population?		N/A
1.2.3	Is it complied with the requirements of employed directive or manufacturer declares limits for sample tested?		P
1.3	Requirements of test report		P
1.3.1	Is it included the information of manufacturer, sample, test lab or etc?		P
1.3.2	Is it clearly specified the test object as the port of components or product?		P
1.3.3	Is it described the information of directive or standards of test methods?		P
1.3.4	Is it described the results with accurately for interpretation, using or etc?		P
1.3.5	Is it confirmed the validity of test equipment and information of calibration?		P
1.4	Other information		
	Directive 2011/65/EU EN 50581 : 2012 EN 62321 : 2009 EN 62474 : 2012 IEC/TR 62476 : 2010		

Appendix I Photos of product



Product View

Appendix II Test method & Lab information

1. General

1.1 Standard: EN 50581 : 2012, EN 62321 : 2009

1.2 Applied sampling criteria

-Kind of components could be disassembled mechanically by using disassembly tools

- High risk components

2. Laboratory Information

- Laboratory's Name : Standard Engineering

- Address : 145, Hwanggeumteo-gil, Eumam-myeon, Seosan-si, Chungcheongnam-do, KOREA - Tel.: +82-41-663-9436, Fax :+82-41-663-9434

- Facilities used :

i) X-Ray Fluorescence Spectrometer (XRF)

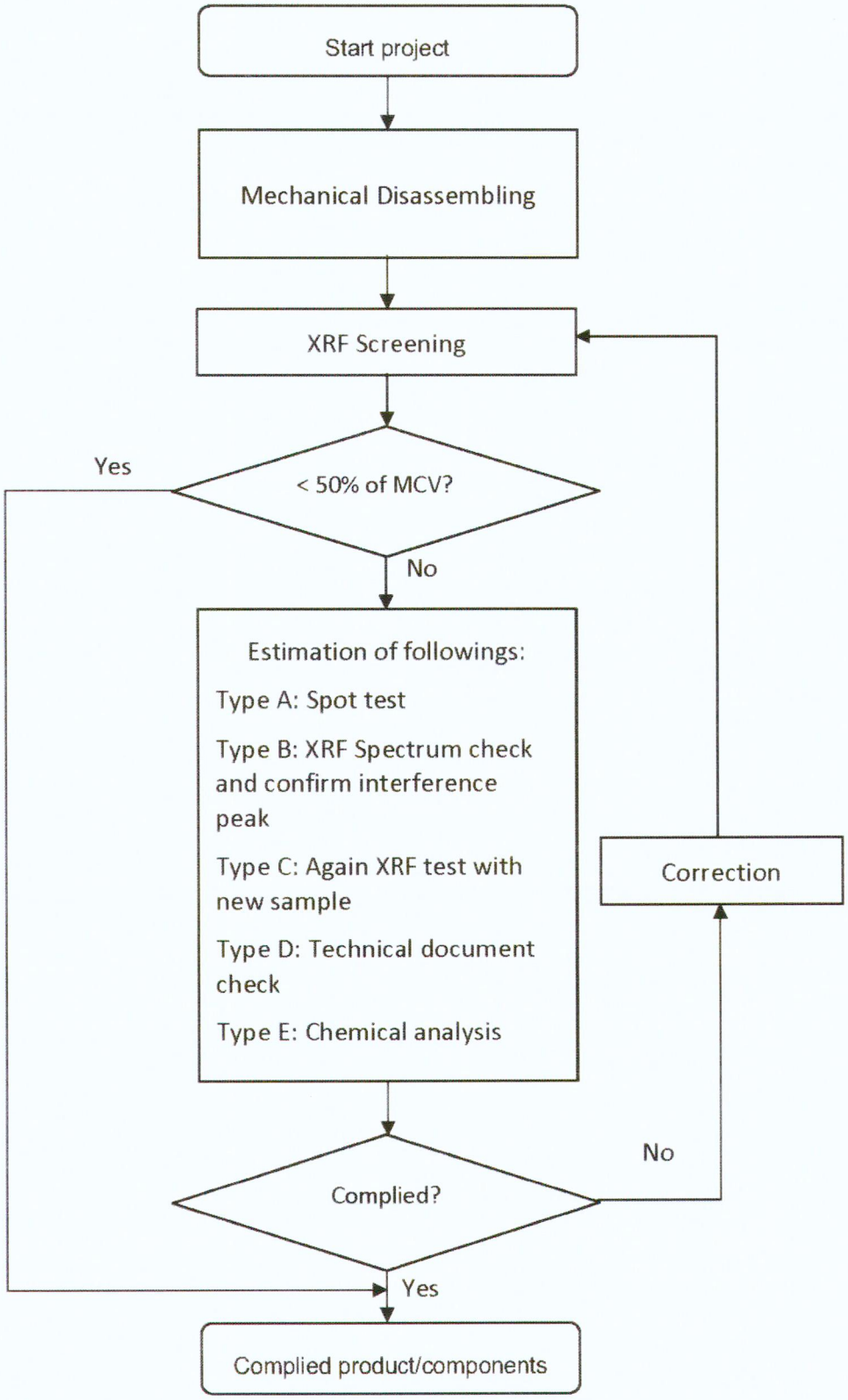
ii) Maker : ISP

iii) Model : iEDX-100A

3. Product Remark

Specification of Product	**Product**	**Diagnostic device of human infection by Helicobacter pylory bacteria**
	Main Model name	**GastroTest**
	Variant Model name	**N/A**

Appendix III Verification Test Results



Appendix III Verification Test Results

No	Part name		Supplier	XRF Data (mg/kg)					Estimation	Result
				Cd	Pb	Hg	Br	Cr		
1.1	Screw	Metal Fe	-	0	166	0	0	0	Type A	Pass
1.2	Screw	Metal CuNi	-	0	56	34	0	0	Type A	Pass
1.3	Screw	Metal CuN	-	0	33	0	0	182	N/A	Pass
1.4	Spring	Metal Fe	-	0	165	0	0	466	N/A	Pass
1.5	Enclosure	Plastic PE	-	0	0	0	0	0	N/A	Pass

Appendix IV Remark

1. Results are obtained by ED XRF in regulated substances according to IEC 62321;2008 Sec. 6 & Annex D.

2. It is the result on total Br while test item on restricted substances is PBBs & PBDEs.
Also, it is the result on total Cr while test item on restricted substance is hexavalent chromium.

3. Screening limits in mg/kg for regulated elements in various matrices

Element	Polymers	Metals	Composite materials
Cd	BL ≤ (70-3σ)< X < (130+3σ) ≤ OL	BL ≤ (70-3σ)< X < (130+3σ) ≤ OL	LOD < X < (150+3σ) ≤ OL
Pb	BL ≤ (700-3σ)< X < (1 300+3σ) ≤ OL	BL ≤ (700-3σ)< X < (1 300+3σ) ≤ OL	BL ≤ (500-3σ)< X < (1 500+3σ) ≤ OL
Hg	BL ≤ (700-3σ)< X < (1 300+3σ) ≤ OL	BL ≤ (700-3σ)< X < (1 300+3σ) ≤ OL	BL ≤ (500-3σ)< X < (1 500+3σ) ≤ OL
Br	BL ≤ (300-3σ)< X	N/A	BL ≤ (250-3σ)< X
Cr	BL ≤ (700-3σ)< X	BL ≤ (700-3σ)< X	BL ≤ (500-3σ)< X

* note ; BL = Below limit, OL = Over limit, X = Inconclusive

4. The estimation criteria of XRF Screening result applied 50% of MCV (Maximum concentration value) which is defined in 2011/65/EU RoHS Directive.

Item	Cd	Pb	Hg	Br (PBBs, PBDEs)	Cr (Cr 6+)
MCV	100	1000	1000	1000	1000
Estimation criteria	50	500	500	500	500

-The additional Investigation procedure is taken when doubtful test result detected more than 50% of MCV. 5. The type of estimation

5. The type of estimation

Type A	Detected more than 50% of MCV of total Cr and confirmed absence of Cr6+ by diphenylcarbazide reagent.
Type B	Checked XRF spectrum and confirmed interference peak
Type C	Primary test result failed and replaced new sample. Finally confirmed through again XRF test.
Type D	Detected more than 50% of MCV on total Br and confirmed absence PBBs/PBDEs through technical document of detected parts or material.
Type E	Detected parts or material was conducted by chemical analysis

Appendix V Reference document

1. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

2. EN 50581 : 2012
Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.

3. EN 62321 : 2009
Electrotechnical products–determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers.)

4. EN 62474 : 2012
Material declaration for products of and for the electrotechnical industry.

5. IEC/TR 62476 : 2010
Guidance for evaluation of products with respect to substance use restriction in electrical and electronic products.

~~ THE END ~~