Number: PM-SPN-27-0007 Version: 6.0 Status: Approved Approved Date: 18 May 2022

Microscope Slide Coverslips Part 3 - IVDR Declaration of Conformity (DoC)

#### **EU Declaration of Conformity**

To IVD REGULATION (EU) 2017/746



Legal Manufacturer's Name:

New Erie Scientific LLC

Legal Manufacturer's Address:

20 Post Road, Portsmouth, NH 03801 USA

SRN (Single Registration Number):

US-MF-000008165

New Erie Scientific LLC declares that the In Vitro Diagnostic Medical Devices listed in this declaration are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices and are therefore entitled to bear the CE Mark.

Product Trade Name	Microscope Slide Coverslips
Intended Purpose	Microscope slide coverslips are suitable for cellular and tissue specimen preparation for microscopic analysis intended for diagnostic use.  Microscope slide coverslips serve as a physical barrier to protect the specimen from mechanical forces and environmental exposure.
Classification & Classification Rules	Class A, Rule 5, Indent (a) per EU IVDR 2017/746.
Conformity Assessment Route	In accordance with Article 17 and Annex IV of IVDR 2017/746
Product Number	See Appendix 1
Basic UDI-DI	081004133NES002MQ
Nomenclature	15687
Initial CE Release Date	Year 2000
Authorized Representative Name and Address	Epredia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands.
Authorized Representative SRN	NL-AR-000001488

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	
-----------	------------------------------	------------------------	----------------	--------------------------	--

Number: PM-SPN-27-0007 Version: 6.0 Status: Approved Approved Date: 18 May 2022

Microscope Slide Coverslips Part 3 - IVDR Declaration of Conformity (DoC)

#### **EU Declaration of Conformity**

To IVD REGULATION (EU) 2017/746



We hereby declare under our sole responsibility that these products conform with the relevant provisions of the EU IVD Regulation 2017/746.

We confirm that the CE-marked IVDs listed in the appendix are manufactured under a controlled and approved Quality Management System that maintains a post market surveillance and vigilance procedure. Each of the listed CE-marked IVD has been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Annex I in the EU IVDR 2017/746 prior to being placed on the market.

Approved by:

Mark Ramser

Vice President, Quality & Regulatory

Place of Issue: Kalamazoo, US

Date of Issue: 13-May-2022

Revision: 01

Form Name

**EU Declaration of Conformity** 

Form (Template) Number

GL-FRM-27-0003

Form Template Version

2.0

Number: PM-SPN-27-0007 Version: 6.0 Status: Approved Approved Date: 18 May 2022

Microscope Slide Coverslips Part 3 - IVDR Declaration of Conformity (DoC)

### **EU Declaration of Conformity**

To IVD REGULATION (EU) 2017/746



#### Appendix 1 – Device Information:

No.	Product Name	Part Numbers		
1	Cover Slips	BC23450620A133MNZ1		
2	Cover Slips	BB02400500A113MNZ0		
3	Cover Slips	BB02200220A153MNZ0		
4	Cover Slips	BB02400600A113MNZ0		
5	Cover Slips	BB01800180A153MNZ0		
6	Cover Slips	BB02000200A153MNZ0		
7	Cover Slips	BB01800180A123MNZ0		
8	Cover Slips	BB02400400A113MNZ0		
9	Cover Slips	BB02400500S113MNZ0		
10	Cover Slips	BB02200220A123MNZ0		
11	Cover Slips	BB02200400A113AUT0		
12	Cover Slips	BB02400240A153MNZ0		
13	Cover Slips	BB02400320A113MNZ0		
14	Cover Slips	CB00090RA120AUT0		
15	Cover Slips	BB02200220A123AUT0		
16	Cover Slips	BB02400500A113AUT0		
17	Cover Slips	BB02400400A133MNZ0		
18	Cover Slips	BB02400500SC13MNZ0		
19	Cover Slips	BB01800180A153FST0		
20	Cover Slips	BB02200320A113MNZ0		
21	Cover Slips	BB02400500AC13MNZ0		
22	Cover Slips	BB02400240AC53FST0		
23	Cover Slips	BB02400500A113FST0		
24	Cover Slips	BB02200500A113AUT0		
25	Cover Slips	BB02200220A153FST0		
26	Cover Slips	BB02200500A113MNZ0		
27	Cover Slips	BE02200500A163MNZ0		
28	Cover Slips	CB00120RA120MNZ0		
29	Cover Slips	BB02400550A113MNZ0		
30	Cover Slips	BB02400600A113FST0		

Form Name EU Declaration of Conformity Form (Template) Number GL-FR	Form Template Version 2.	2.0
---	--------------------------	-----



31	Cover Slips	BB02400600AC13MNZ0
32	Cover Slips	BB01500150A1D3MNZ0
33	Cover Slips	BB02200400A113MNZ0
34	Cover Slips	BB02400240AC23MNZ0
35	Cover Slips	BB02400500A133MNZ0
36	Cover Slips	BB02000200A123MNZ0
37	Cover Slips	BB02400240A123MNZ0
38	Cover Slips	BE02200220A163MNZ0
39	Cover Slips	CB00120RAC20MNZ0
40	Cover Slips	BB02100260A113MNZ0
41	Cover Slips	CB00180RA120MNZ0
42	Cover Slips	BB02400360A113MNZ0
43	Cover Slips	BB02400600A113AUT0
44	Cover Slips	BB02200220AC53MNZ0
45	Cover Slips	BE02400600A163MNZ0
46	Cover Slips	BB02200220AC23MNZ0
47	Cover Slips	BE02400400A163MNZ0
48	Cover Slips	CB00100RA120MNZ0
49	Cover Slips	BB02400240A153FST0
50	Cover Slips	CB00130RA120MNZ0
51	Cover Slips	BB02400400A113AUT0
52	Cover Slips	BB01800180A120MNZ1
53	Cover Slips	BB01800180A150MNZ0
54	Cover Slips	BB02200320AC13MNZ0
55	Cover Slips	BB02200320A113AUT0
56	Cover Slips	BB02000200A153FST0
57	Cover Slips	BB02400600S113MNZ0
58	Cover Slips	BB02000200A153MNZ1
59	Cover Slips	BB02000200A1D3MNZ0
60	Cover Slips	BB02400320A113FST0
61	Cover Slips	BB02400460A113MNZ0
62	Cover Slips	BC02600760A140MNZ1
63	Cover Slips	BB02200220A153MNZ1

	Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	1/11
L						



64	Cover Slips	BB02200220AC23AUT0
65	Cover Slips	CB00150RA120MNZ0
66	Cover Slips	CB00130RAC20MNZ0
67	Cover Slips	BB02400600SC13MNZ0
68	Cover Slips	BB02200320AC13AUT0
69	Cover Slips	BB02200400A133MNZ0
70	Cover Slips	BB01800180AC20MNZ0
71	Cover Slips	BB02400400AC13MNZ0
72	Cover Slips	BE02200400A163MNZ0
73	Cover Slips	BB02200400AC13NZT0
74	Cover Slips	BB02400400S113MNZ0
75	Cover Slips	BB02200600A113FST0
76	Cover Slips	CB00050RA120MNZ0
77	Cover Slips	BB02200600A233MNZ0
78	Cover Slips	BB02200600AC13AUT0
79	Cover Slips	BB02400240A123AUT0
80	Cover Slips	BB02400240A1D3MNZ0
81	Cover Slips	BC06351183A140MNZ1
82	Cover Slips	BB02400320A233MNZ0
83	Cover Slips	CB00180RAC20MNZ0
84	Cover Slips	CB00250RAC33MNZ0
85	Cover Slips	CB00140RA120MNZ0
86	Cover Slips	BB02400400A113MNZ1
87	Cover Slips	BC05100750A140MNZ0
88	Cover Slips	BB02400400A183MNZ0
89	Cover Slips	BB02400400A213MNZ0
90	Cover Slips	BB02400550S113MNZ0
91	Cover Slips	CB00130RA020FST0
92	Cover Slips	BB02000200AC53FST0
93	Cover Slips	BB02500500A113MNZ0
94	Cover Slips	CB00080RA120MNZ0
95	Cover Slips	BB02400500A113MNZ1
96	Cover Slips	BB02400320AC13MNZ0

Form Name   EU Declaration of Conformity   Form (Template) Number   GL-FRM-27-0003   Version   2.0	Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0
--	-----------	------------------------------	------------------------	----------------	--------------------------	-----

# **EU Declaration of Conformity**



97	Cover Slips	CB00150RAC20MNZ0
98	Cover Slips	BB01800180A123AUT0
99	Cover Slips	BB02200220AC53FST0
100	Cover Slips	BB02400550SC13MNZ0
101	Cover Slips	BB02200400AC13MNZ0
102	Cover Slips	BB02400600A113CML0
103	Cover Slips	BC02200260A113MNZ0
104	Cover Slips	BB02200220A223MNZ0
105	Cover Slips	BB02400600A113MNZ1
106	Cover Slips	BB02200500A113FST0
107	Cover Slips	BB02400500A033MNZ0
108	Cover Slips	CB00240RA120MNZ0
109	Cover Slips	CB00100RA020MNZ0
110	Cover Slips	BB02400500A183MNZ0
111	Cover Slips	BB02400400A113FST0
112	Cover Slips	CB00200RA120MNZ0
113	Cover Slips	BC02400650A133MNZ0
114	Cover Slips	BB02400600SC13MNZ2
115	Cover Slips	BB02400600SC33MNZ0
116	Cover Slips	BB02500400A233MNZ0
117	Cover Slips	CB00100RAC20MNZ0
118	Cover Slips	CB00220RA120MNZ0
119	Cover Slips	CB00060RA120MNZ0
120	Cover Slips	BB02200600A113MNZ0
121	Cover Slips	BB02400600A033MNZ0
122	Cover Slips	BC02200640A133AUT0
123	Cover Slips	BB02200400AC13AUT0
124	Cover Slips	BC02400260A113MNZ0
125	Cover Slips	BC02400640A133MNZ0
126	Cover Slips	BC05000600A140MNZ0
127	Cover Slips	BE02200300A163MNZ0
128	Cover Slips	BC02500320A113MNZ0
129	Cover Slips	BB02200500AC13AUT0

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	
				Version	



130	Cover Slips	BC02400640A133AUT0
131	Cover Slips	BC05000650A140MNZ0
132	Cover Slips	CB00120RA120AUT0
133	Cover Slips	BB01500150A123MNZ0
134	Cover Slips	BB02400600AC13FST0
135	Cover Slips	BB02400240AC53MNZ0
136	Cover Slips	CB00090RA120MNZ0
137	Cover Slips	BB02100260A113FST0
138	Cover Slips	CB00150RAC20FST0
139	Cover Slips	BC02200640A133MNZ0
140	Cover Slips	CB00320RA140MNZ0
141	Cover Slips	BB01500150A1D3FST0
142	Cover Slips	CB00250RA133MNZ0
143	Cover Slips	BB02400360AC13MNZ0
144	Cover Slips	BB01800180AC53MNZ0
145	Cover Slips	BB02200500AC13MNZ0
146	Cover Slips	CB00300RAC40MNZ0
147	Cover Slips	CB00160RA120MNZ0
148	Cover Slips	BB02500600A113MNZ0
149	Cover Slips	BE02200700A173MNZ0
150	Cover Slips	BE02400500A073MNZ0
151	Cover Slips	BE02400500A163MNZ0
152	Cover Slips	BE02500600A173MNZ0
153	Cover Slips	CB00100RA120AUT0
154	Cover Slips	BB01800240A153MNZ0
155	Cover Slips	CB00090RA020MNZ0
156	Cover Slips	CB00400RA140MNZ0
157	Cover Slips	BB02000200AC53MNZ0
158	Cover Slips	BB02400320A133MNZ0
159	Cover Slips	BB02000200AC23MNZ0
160	Cover Slips	CB00115RA220MNZ0
161	Cover Slips	BB02400320A113AUT0
162	Cover Slips	BB02400600A133MNZ0

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0



163	Cover Slips	BB02200220A2D3MNZ0
164	Cover Slips	CB00150RA020MNZ0
165	Cover Slips	CB00300RA140MNZ0
166	Cover Slips	CB00160RA120FST0
167	Cover Slips	CB00180RA020MNZ0
168	Cover Slips	BB02200400A113FST0
169	Cover Slips	CB00120RA020MNZ0
170	Cover Slips	CB00250RA033MNZ0
171	Cover Slips	CB00210RA020MNZ0
172	Cover Slips	CB00220RAC20MNZ0
173	Cover Slips	CB00350RA140MNZ0
174	Cover Slips	CB00250RAC33AUT0
175	Cover Slips	CB00340RA240MNZ0
176	Cover Slips	CB00340RAC40MNZ0
177	Cover Slips	CB00350RA040MNZ0
178	Cover Slips	BB02200320A113FST0
179	Cover Slips	BB02200600A113AUT0
180	Cover Slips	CB00400RA240MNZ0
181	Cover Slips	CB00500RA140MNZ0
182	Cover Slips	CB00470RAC40MNZ0
183	Cover Slips	CB00180RA120AUT0
184	Cover Slips	BB02400400M113CMD0
185	Cover Slips	BB02400500A233MNZ0
186	Cover Slips	CB00130RA020MNZ0
187	Cover Slips	BB01800180AC53FST0
188	Cover Slips	BC04400680A140MNZ0
189	Cover Slips	BB02100260A133MNZ0
190	Cover Slips	BB02400400SC13MNZ0
191	Cover Slips	CB00220RA223MNZ0
192	Cover Slips	CB00120RAC20AUT0
193	Cover Slips	CB00190RA120MNZ0
194	Cover Slips	CB00120RA220MNZ0
195	Cover Slips	BB02200320AC13FST0

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0	AND REAL PROPERTY OF THE PARTY
						4

## **EU Declaration of Conformity**



196	Cover Slips	BB02200500AC13FST0
197	Cover Slips	BB02400500AC13AUT0
198	Cover Slips	BB02400550A113AUT0
199	Cover Slips	BB02400600AC13AUT0
200	Cover Slips	CB00060RA020MNZ0
201	Cover Slips	CB00080RA120AUT0
202	Cover Slips	CB00130RA120AUT0
203	Cover Slips	CB00050RA120AUT0
204	Cover Slips	BE02500600A173AUT0
205	Cover Slips	BB02200600AC13MNZ0
206	Cover Slips	BC04400640AC40MNZ0
207	Cover Slips	CB00190RAC20MNZ0
208	Cover Slips	BB01800240A123MNZ0
209	Cover Slips	BB02400550AC13MNZ0
210	Cover Slips	BC02600760A140MNZ0
211	Cover Slips	BC05400700A140MNZ0
212	Cover Slips	CB00190RA020MNZ0
213	Cover Slips	CB00250RA233MNZ0
214	Cover Slips	BB01800180A220MNZ0
215	Cover Slips	BB01800180A223FST0
216	Cover Slips	BB01800240AC23MNZ0
217	Cover Slips	BB02200400AC13FST0
218	Cover Slips	BB01800180A2D3MNZ0
219	Cover Slips	CB00190RA120FST0
220	Cover Slips	CB00220RAC20FST0
221	Cover Slips	BB02400480A113MNZ0
222	Cover Slips	BC02200640AC33MNZ0
223	Cover Slips	CB00080RA020MNZ0
224	Cover Slips	BB01500150A1D3AUT0
225	Cover Slips	CB00250RA133AUT0
226	Cover Slips	CB00190RA120AUT0
227	Cover Slips	CB00150RA220MNZ0
228	Cover Slips	CB00190RA220MNZ0

-	Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0
ı					VCISIOII	



229	Cover Slips	CB00200RAC20MNZ0
230	Cover Slips	BB01500150A2D3MNZ0
231	Cover Slips	CB00180RA220MNZ0
232	Cover Slips	CB00220RA120AUT0
233	Cover Slips	CB00150RA120AUT0
234	Cover Slips	CB00180RAC20AUT0
235	Cover Slips	CB00200RA020MNZ0
236	Cover Slips	CB00160RA120AUT0
237	Cover Slips	BE02200700A173AUT0
238	Cover Slips	BB01500150A223MNZ0
239	Cover Slips	BB02200320A113NZT0
240	Cover Slips	BB02400400A233MNZ0
241	Cover Slips	BB02400600A233MNZ0
242	Cover Slips	BB02400600SC13FST0
243	Cover Slips	BC03500640A140MNZ0
244	Cover Slips	BC05200720A140MNZ0
245	Cover Slips	BC05700640A140MNZ0
246	Cover Slips	BC07701120A240MNZ0
247	Cover Slips	CB00420RA140MNZ0
248	Cover Slips	CB00470RA140MNZ0
249	Cover Slips	CB00350RAC40MNZ0
250	Cover Slips	BC06601000A140MNZ1
251	Cover Slips	BC02200250A133AUT0
252	Cover Slips	BC02200250A133MNZ0
253	Cover Slips	BC02200260A233MNZ0
254	Cover Slips	BC02200300A113MNZ0
255	Cover Slips	BC02200440A233MNZ0
256	Cover Slips	BC02200490AC13MNZ0
257	Cover Slips	BC02200710A140MNZ0
258	Cover Slips	BC02400440A113MNZ0
259	Cover Slips	BC02400650AC33MNZ0
260	Cover Slips	BC02400730A140MNZ0
261	Cover Slips	BC02400740A140MNZ0

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0

## **EU Declaration of Conformity**



262	Cover Slips	BC02400740AC40MNZ0
263	Cover Slips	BC02400750A140MNZ0
264	Cover Slips	BC02500250A233MNZ0
265	Cover Slips	BC02500550A113MNZ0
266	Cover Slips	BC02500750A240MNZ0
267	Cover Slips	BC03500550AC40MNZ0
268	Cover Slips	BC04800640A140MNZ0
269	Cover Slips	BC05000700A140MNZ0
270	Cover Slips	BC01800300A133MNZ0
271	Cover Slips	BC05000750A140MNZ0
272	Cover Slips	BC04400650A140MNZ0
273	Cover Slips	BC04800600A240MNZ0
274	Cover Slips	BC05000640AC40MNZ0
275	Cover Slips	BC05000760A140MNZ0
276	Cover Slips	BC02400700A133MNZ0
277	Cover Slips	BC05000550A140MNZ0
278	Cover Slips	BC02200750A140AUT0
279	Cover Slips	BC02600760AC40MNZ0
280	Cover Slips	BC02200260A113FST0
281	Cover Slips	BC02500250A113MNZ0
282	Cover Slips	BC04400440A140MNZ0
283	Cover Slips	BC02200260AC13FST0
284	Cover Slips	BC02700470A140MNZ0
285	Cover Slips	BC04000600A140MNZ0
286	Cover Slips	BC05000500AC40MNZ0
287	Cover Slips	BC02500700A140MNZ0
288	Cover Slips	BC08500950A140MNZ0
289	Cover Slips	BC02200700A133MNZ0
290	Cover Slips	BC04000500A140MNZ0
291	Cover Slips	BC04500720A140MNZ0
292	Cover Slips	BC02600600A140MNZ0
293	Cover Slips	BC03200320A140MNZ0
294	Cover Slips	BC04500750A140MNZ0

Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0
-----------	------------------------------	------------------------	----------------	--------------------------	-----

# **EU Declaration of Conformity**



v :		
295	Cover Slips	BC04800640AC40MNZ0
296	Cover Slips	BC05600760A140MNZ0
297	Cover Slips	BC10001000A140MNZ0
298	Cover Slips	BC02500750AC40MNZ0
299	Cover Slips	BC03500500A140MNZ0
300	Cover Slips	BC03500640AC40MNZ0
301	Cover Slips	BC04500500AC40MNZ0
302	Cover Slips	BC04500650A140MNZ0
303	Cover Slips	BC05000640A140MNZ0
304	Cover Slips	BC05200760A140MNZ0
305	Cover Slips	BC06700840A140MNZ0
306	Cover Slips	BC08801000A140MNZ0
307	Cover Slips	BC02200260AC13MNZ0
308	Cover Slips	BC02500250AC33MNZ0
309	Cover Slips	BC02500750A140MNZ0
310	Cover Slips	BC02600460A140MNZ0
311	Cover Slips	BC03000450A140MNZ0
312	Cover Slips	BC03500350AC40MNZ0
313	Cover Slips	BC03500600A140MNZ0
314	Cover Slips	BC03800380A140MNZ0
315	Cover Slips	BC03800750AC40MNZ0
316	Cover Slips	BC04500600A140MNZ0
317	Cover Slips	BC04800480A140MNZ0
318	Cover Slips	BC05200750A140MNZ0
319	Cover Slips	BC05800750A140MNZ0
320	Cover Slips	BC07501100A140MNZ0
321	Cover Slips	BC08000800A140MNZ0

				Form Tomplete	
Form Name	EU Declaration of Conformity	Form (Template) Number	GL-FRM-27-0003	Form Template Version	2.0