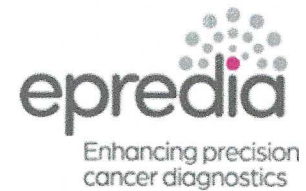


EU Declaration of Conformity

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

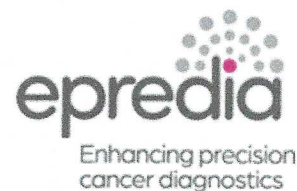
New Erie Scientific LLC declares that the In Vitro Diagnostic Medical Devices listed in this declaration are in conformity with all applicable provisions of Council Regulation (EU) 2017/746 of 5 April 2017 on In Vitro Diagnostic Medical Devices and are therefore entitled to bear the CE Mark.

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

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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

A handwritten signature in black ink, appearing to read "Mark Ramser", written over a light blue horizontal line.

Place of Issue: Kalamazoo, US

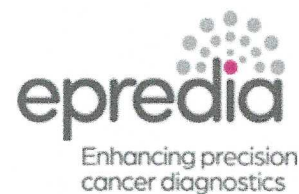
Date of Issue: 13-May-2022

Revision: 01

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

TO IVD REGULATION (EU) 2017/746



• Appendix 1 – Device Information:

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9	Cover Slips	BB02400500S113MNZO
10	Cover Slips	BB02200220A123MNZO
11	Cover Slips	BB02200400A113AUTO
12	Cover Slips	BB02400240A153MNZO
13	Cover Slips	BB02400320A113MNZO
14	Cover Slips	CB00090RA120AUTO
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16	Cover Slips	BB02400500A113AUTO
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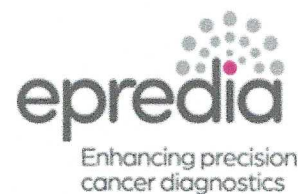


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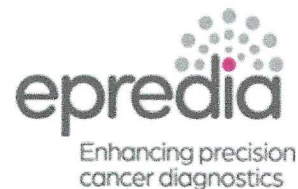


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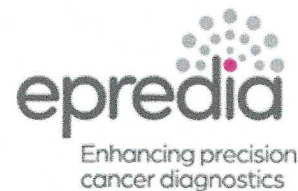


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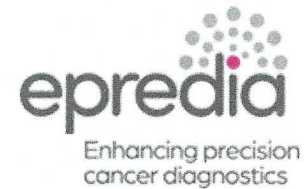


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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746

Nazwa producenta: New Erie Scientific LLC

Adres producenta: 20 Post Road, Portsmouth, NH 03801 USA

SRN (Single Registration Number): US-MF-000008165

New Erie Scientific LLC, spółka zależna Epredia, oświadcza, że wyroby medyczne do diagnostyki *in vitro* wymienione w niniejszej deklaracji są zgodne ze wszystkimi obowiązującymi przepisami rozporządzenia Rady (UE) 2017/746 z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki *in vitro* i są w związku z tym uprawnione do noszenia znaku CE.

Produkt i nazwa handlowa	Szkiełka nakrywkowe
Przeznaczenie wyrobu	Szkiełka nakrywkowe są odpowiednie do przygotowywania próbek komórkowych i tkankowych do analizy mikroskopowej przeznaczonej do użytku diagnostycznego. Szkiełka nakrywkowe służą jako fizyczna bariera chroniąca próbkę przed siłami mechanicznymi i oddziaływaniem środowiska.
Klasyfikacja & Zasady klasyfikacji	Klasa A, Zasada 5, Akapit (a) zgodnie z EU IVDR 2017/746
Numer produktu	Zgodnie z Załącznikiem 1
Basic UDI-DI	081004133NES002MQ
Nomenklatura	15687
Pierwsza data wydania CE	2000
Nazwa i adres autoryzowanego przedstawiciela	Epredia Netherlands B.V. Essendonk 30, 4824 DA Breda, Netherlands.
Autoryzowany Przedstawiciel SRN	NL-AR-000001488

Nazwa formularza	Deklaracja zgodności	Numer (szablonu) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



Niniejszym oświadczamy z pełną odpowiedzialnością, że te produkty są zgodne z odpowiednimi przepisami rozporządzenia UE IVD 2017/746.

Potwierdzamy, że wymienione w załączniku produkty do diagnostyki in vitro z oznaczeniem CE są produkowane w ramach kontrolowanego i zatwierdzonego Systemu Zarządzania Jakością, który utrzymuje procedurę nadzoru i czujności po wprowadzeniu do obrotu. Każdy z wymienionych produktów IVD oznaczonych znakiem CE został zweryfikowany pod kątem określonych kryteriów i uznany za zgodny z wymaganiami ogólnymi dotyczącymi bezpieczeństwa i działania z załącznika | w UE 2017/746 przed wprowadzeniem do obrotu.

Zatwierdzone przez:

Mark Ramser

Wiceprezes ds. Jakości i Regulacji

Miejsce wydania: Kalamazoo, USA

Data wydania: 13-maj-2022

Rewizja: 1.0

ElektroMed™



Nazwa formularza	Deklaracja zgodności	Numer (szablону) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



- Załącznik 1 - Informacje o wyrobach**

No.	Product Name	Part Numbers
1	Cover Slips	BC23450620A133MNZ1
2	Cover Slips	BB02400500A113MNZO
3	Cover Slips	BB02200220A153MNZO
4	Cover Slips	BB02400600A113MNZO
5	Cover Slips	BB01800180A153MNZO
6	Cover Slips	BB02000200A153MNZO
7	Cover Slips	BB01800180A123MNZO
8	Cover Slips	BB02400400A113MNZO
9	Cover Slips	BB02400500S113MNZO
10	Cover Slips	BB02200220A123MNZO
11	Cover Slips	BB02200400A113AUTO
12	Cover Slips	BB02400240A153MNZO
13	Cover Slips	BB02400320A113MNZO
14	Cover Slips	CB00090RA120AUTO
15	Cover Slips	BB02200220A123AUTO
16	Cover Slips	BB02400500A113AUTO
17	Cover Slips	BB02400400A133MNZO
18	Cover Slips	BB02400500SC13MNZO
19	Cover Slips	BB01800180A153FSTO
20	Cover Slips	BB02200320A113MNZO
21	Cover Slips	BB02400500AC13MNZO
22	Cover Slips	BB02400240AC53FSTO
23	Cover Slips	BB02400500A113FSTO
24	Cover Slips	BB02200500A113AUTO
25	Cover Slips	BB02200220A153FSTO
26	Cover Slips	BB02200500A113MNZO
27	Cover Slips	BE02200500A163MNZO
28	Cover Slips	CB00120RA120MNZO
29	Cover Slips	BB02400550A113MNZO
30	Cover Slips	BB02400600A113FSTO

Nazwa formularza	Deklaracja zgodności	Numer (szablону) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



31	Cover Slips	BB02400600AC13MNZO
32	Cover Slips	BB01500150A1D3MNZO
33	Cover Slips	BB02200400A113MNZO
34	Cover Slips	BB02400240AC23MNZO
35	Cover Slips	BB02400500A133MNZO
36	Cover Slips	BB02000200A123MNZO
37	Cover Slips	BB02400240A123MNZO
38	Cover Slips	BE02200220A163MNZO
39	Cover Slips	CB00120RAC20MNZO
40	Cover Slips	BB02100260A113MNZO
41	Cover Slips	CB00180RA120MNZO
42	Cover Slips	BB02400360A113MNZO
43	Cover Slips	BB02400600A113AUTO
44	Cover Slips	BB02200220AC53MNZO
45	Cover Slips	BE02400600A163MNZO
46	Cover Slips	BB02200220AC23MNZO
47	Cover Slips	BE02400400A163MNZO
48	Cover Slips	CB00100RA120MNZO
49	Cover Slips	BB02400240A153FSTO
50	Cover Slips	CB00130RA120MNZO
51	Cover Slips	BB02400400A113AUTO
52	Cover Slips	BB01800180A120MNZ1
53	Cover Slips	BB01800180A150MNZO
54	Cover Slips	BB02200320AC13MNZO
55	Cover Slips	BB02200320A113AUTO
56	Cover Slips	BB02000200A153FSTO
57	Cover Slips	BB02400600S113MNZO
58	Cover Slips	BB02000200A153MNZ1
59	Cover Slips	BB02000200A1D3MNZO
60	Cover Slips	BB02400320A113FSTO
61	Cover Slips	BB02400460A113MNZO
62	Cover Slips	BC02600760A140MNZ1
63	Cover Slips	BB02200220A153MNZ1

Nazwa formularza	Deklaracja zgodności	Numer (szablonu) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



64	Cover Slips	BB02200220AC23AUTO
65	Cover Slips	CB00150RA120MNZO
66	Cover Slips	CB00130RAC20MNZO
67	Cover Slips	BB02400600SC13MNZO
68	Cover Slips	BB02200320AC13AUTO
69	Cover Slips	BB02200400A133MNZO
70	Cover Slips	BB01800180AC20MNZO
71	Cover Slips	BB02400400AC13MNZO
72	Cover Slips	BE02200400A163MNZO
73	Cover Slips	BB02200400AC13NZTO
74	Cover Slips	BB02400400S113MNZO
75	Cover Slips	BB02200600A113FSTO
76	Cover Slips	CB00050RA120MNZO
77	Cover Slips	BB02200600A233MNZO
78	Cover Slips	BB02200600AC13AUTO
79	Cover Slips	BB02400240A123AUTO
80	Cover Slips	BB02400240A1D3MNZO
81	Cover Slips	BC06351183A140MNZ1
82	Cover Slips	BB02400320A233MNZO
83	Cover Slips	CB00180RAC20MNZO
84	Cover Slips	CB00250RAC33MNZO
85	Cover Slips	CB00140RA120MNZO
86	Cover Slips	BB02400400A113MNZ1
87	Cover Slips	BC05100750A140MNZO
88	Cover Slips	BB02400400A183MNZO
89	Cover Slips	BB02400400A213MNZO
90	Cover Slips	BB02400550S113MNZO
91	Cover Slips	CB00130RA020FSTO
92	Cover Slips	BB02000200AC53FSTO
93	Cover Slips	BB02500500A113MNZO
94	Cover Slips	CB00080RA120MNZO
95	Cover Slips	BB02400500A113MNZ1
96	Cover Slips	BB02400320AC13MNZO

Nazwa formularza	Deklaracja zgodności	Numer (szablonu) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



97	Cover Slips	CB00150RAC20MNZO
98	Cover Slips	BB01800180A123AUTO
99	Cover Slips	BB02200220AC53FSTO
100	Cover Slips	BB02400550SC13MNZO
101	Cover Slips	BB02200400AC13MNZO
102	Cover Slips	BB02400600A113CML0
103	Cover Slips	BC02200260A113MNZO
104	Cover Slips	BB02200220A223MNZO
105	Cover Slips	BB02400600A113MNZ1
106	Cover Slips	BB02200500A113FSTO
107	Cover Slips	BB02400500A033MNZO
108	Cover Slips	CB00240RA120MNZO
109	Cover Slips	CB00100RA020MNZO
110	Cover Slips	BB02400500A183MNZO
111	Cover Slips	BB02400400A113FSTO
112	Cover Slips	CB00200RA120MNZO
113	Cover Slips	BC02400650A133MNZO
114	Cover Slips	BB02400600SC13MNZ2
115	Cover Slips	BB02400600SC33MNZO
116	Cover Slips	BB02500400A233MNZO
117	Cover Slips	CB00100RAC20MNZO
118	Cover Slips	CB00220RA120MNZO
119	Cover Slips	CB00060RA120MNZO
120	Cover Slips	BB02200600A113MNZO
121	Cover Slips	BB02400600A033MNZO
122	Cover Slips	BC02200640A133AUTO
123	Cover Slips	BB02200400AC13AUTO
124	Cover Slips	BC02400260A113MNZO
125	Cover Slips	BC02400640A133MNZO
126	Cover Slips	BC05000600A140MNZO
127	Cover Slips	BE02200300A163MNZO
128	Cover Slips	BC02500320A113MNZO
129	Cover Slips	BB02200500AC13AUTO

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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



130	Cover Slips	BC02400640A133AUTO
131	Cover Slips	BC05000650A140MNZO
132	Cover Slips	CB00120RA120AUTO
133	Cover Slips	BB01500150A123MNZO
134	Cover Slips	BB02400600AC13FSTO
135	Cover Slips	BB02400240AC53MNZO
136	Cover Slips	CB00090RA120MNZO
137	Cover Slips	BB02100260A113FSTO
138	Cover Slips	CB00150RAC20FSTO
139	Cover Slips	BC02200640A133MNZO
140	Cover Slips	CB00320RA140MNZO
141	Cover Slips	BB01500150A1D3FSTO
142	Cover Slips	CB00250RA133MNZO
143	Cover Slips	BB02400360AC13MNZO
144	Cover Slips	BB01800180AC53MNZO
145	Cover Slips	BB02200500AC13MNZO
146	Cover Slips	CB00300RAC40MNZO
147	Cover Slips	CB00160RA120MNZO
148	Cover Slips	BB02500600A113MNZO
149	Cover Slips	BE02200700A173MNZO
150	Cover Slips	BE02400500A073MNZO
151	Cover Slips	BE02400500A163MNZO
152	Cover Slips	BE02500600A173MNZO
153	Cover Slips	CB00100RA120AUTO
154	Cover Slips	BB01800240A153MNZO
155	Cover Slips	CB00090RA020MNZO
156	Cover Slips	CB00400RA140MNZO
157	Cover Slips	BB02000200AC53MNZO
158	Cover Slips	BB02400320A133MNZO
159	Cover Slips	BB02000200AC23MNZO
160	Cover Slips	CB00115RA220MNZO
161	Cover Slips	BB02400320A113AUTO
162	Cover Slips	BB02400600A133MNZO

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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



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	CB00250RAC33AUTO
175	Cover Slips	CB00340RA240MNZ0
176	Cover Slips	CB00340RAC40MNZ0
177	Cover Slips	CB00350RA040MNZ0
178	Cover Slips	BB02200320A113FST0
179	Cover Slips	BB02200600A113AUTO
180	Cover Slips	CB00400RA240MNZ0
181	Cover Slips	CB00500RA140MNZ0
182	Cover Slips	CB00470RAC40MNZ0
183	Cover Slips	CB00180RA120AUTO
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	CB00120RAC20AUTO
193	Cover Slips	CB00190RA120MNZ0
194	Cover Slips	CB00120RA220MNZ0
195	Cover Slips	BB02200320AC13FST0

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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



196	Cover Slips	BB02200500AC13FST0
197	Cover Slips	BB02400500AC13AUTO
198	Cover Slips	BB02400550A113AUTO
199	Cover Slips	BB02400600AC13AUTO
200	Cover Slips	CB00060RA020MNZ0
201	Cover Slips	CB00080RA120AUTO
202	Cover Slips	CB00130RA120AUTO
203	Cover Slips	CB00050RA120AUTO
204	Cover Slips	BE02500600A173AUTO
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	BB01500150A1D3AUTO
225	Cover Slips	CB00250RA133AUTO
226	Cover Slips	CB00190RA120AUTO
227	Cover Slips	CB00150RA220MNZ0
228	Cover Slips	CB00190RA220MNZ0

Nazwa formularza	Deklaracja zgodności	Numer (szablonu) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



229	Cover Slips	CB00200RAC20MNZO
230	Cover Slips	BB01500150A2D3MNZO
231	Cover Slips	CB00180RA220MNZO
232	Cover Slips	CB00220RA120AUTO
233	Cover Slips	CB00150RA120AUTO
234	Cover Slips	CB00180RAC20AUTO
235	Cover Slips	CB00200RA020MNZO
236	Cover Slips	CB00160RA120AUTO
237	Cover Slips	BE02200700A173AUTO
238	Cover Slips	BB01500150A223MNZO
239	Cover Slips	BB02200320A113NZTO
240	Cover Slips	BB02400400A233MNZO
241	Cover Slips	BB02400600A233MNZO
242	Cover Slips	BB02400600SC13FSTO
243	Cover Slips	BC03500640A140MNZO
244	Cover Slips	BC05200720A140MNZO
245	Cover Slips	BC05700640A140MNZO
246	Cover Slips	BC07701120A240MNZO
247	Cover Slips	CB00420RA140MNZO
248	Cover Slips	CB00470RA140MNZO
249	Cover Slips	CB00350RAC40MNZO
250	Cover Slips	BC06601000A140MNZ1
251	Cover Slips	BC02200250A133AUTO
252	Cover Slips	BC02200250A133MNZO
253	Cover Slips	BC02200260A233MNZO
254	Cover Slips	BC02200300A113MNZO
255	Cover Slips	BC02200440A233MNZO
256	Cover Slips	BC02200490AC13MNZO
257	Cover Slips	BC02200710A140MNZO
258	Cover Slips	BC02400440A113MNZO
259	Cover Slips	BC02400650AC33MNZO
260	Cover Slips	BC02400730A140MNZO
261	Cover Slips	BC02400740A140MNZO

Nazwa formularza	Deklaracja zgodności	Numer (szablonu) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



262	Cover Slips	BC02400740AC40MNZO
263	Cover Slips	BC02400750A140MNZO
264	Cover Slips	BC02500250A233MNZO
265	Cover Slips	BC02500550A113MNZO
266	Cover Slips	BC02500750A240MNZO
267	Cover Slips	BC03500550AC40MNZO
268	Cover Slips	BC04800640A140MNZO
269	Cover Slips	BC05000700A140MNZO
270	Cover Slips	BC01800300A133MNZO
271	Cover Slips	BC05000750A140MNZO
272	Cover Slips	BC04400650A140MNZO
273	Cover Slips	BC04800600A240MNZO
274	Cover Slips	BC05000640AC40MNZO
275	Cover Slips	BC05000760A140MNZO
276	Cover Slips	BC02400700A133MNZO
277	Cover Slips	BC05000550A140MNZO
278	Cover Slips	BC02200750A140AUTO
279	Cover Slips	BC02600760AC40MNZO
280	Cover Slips	BC02200260A113FSTO
281	Cover Slips	BC02500250A113MNZO
282	Cover Slips	BC04400440A140MNZO
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284	Cover Slips	BC02700470A140MNZO
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286	Cover Slips	BC05000500AC40MNZO
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289	Cover Slips	BC02200700A133MNZO
290	Cover Slips	BC04000500A140MNZO
291	Cover Slips	BC04500720A140MNZO
292	Cover Slips	BC02600600A140MNZO
293	Cover Slips	BC03200320A140MNZO
294	Cover Slips	BC04500750A140MNZO

Nazwa formularza	Deklaracja zgodności	Numer (szablonu) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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Deklaracja Zgodności

Zgodnie z ROZPORZĄDZENIEM IVD (UE) 2017/746



295	Cover Slips	BC04800640AC40MNZO
296	Cover Slips	BC05600760A140MNZO
297	Cover Slips	BC10001000A140MNZO
298	Cover Slips	BC02500750AC40MNZO
299	Cover Slips	BC03500500A140MNZO
300	Cover Slips	BC03500640AC40MNZO
301	Cover Slips	BC04500500AC40MNZO
302	Cover Slips	BC04500650A140MNZO
303	Cover Slips	BC05000640A140MNZO
304	Cover Slips	BC05200760A140MNZO
305	Cover Slips	BC06700840A140MNZO
306	Cover Slips	BC08801000A140MNZO
307	Cover Slips	BC02200260AC13MNZO
308	Cover Slips	BC02500250AC33MNZO
309	Cover Slips	BC02500750A140MNZO
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312	Cover Slips	BC03500350AC40MNZO
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314	Cover Slips	BC03800380A140MNZO
315	Cover Slips	BC03800750AC40MNZO
316	Cover Slips	BC04500600A140MNZO
317	Cover Slips	BC04800480A140MNZO
318	Cover Slips	BC05200750A140MNZO
319	Cover Slips	BC05800750A140MNZO
320	Cover Slips	BC07501100A140MNZO
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Nazwa formularza	Deklaracja zgodności	Numer (szablonu) formularza	GL-FRM-27-0003	Wersja wzoru formularza	2.0
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