



PZ CORMAY S.A.
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 www.cormay.pl office@cormay.pl



EC DECLARATION OF CONFORMITY

In accordance with Directive 98/79/EC

We, **PZ CORMAY S.A.**, 22 Wiosenna Str., 05-092 Lomianki, Poland, declare that the following devices:

Devices name: See ATTACHMENT 1

Devices number: See ATTACHMENT 1

(classified as other IVDD – all devices with exception of devices listed in List A and List B and self-testing devices) comply with essential requirements of the ANNEX I – Directive 98/79/EC and their conformity assessment has been made according to the ANNEX III – Directive 98/79/EC.

The devices named above have been designed and manufactured according to the specifications:

- | | |
|---------------------|--|
| EN 980:2008 | Graphical symbols for use in the labelling of medical devices. |
| EN ISO 15223-1:2012 | Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements. |
| EN 13612:2002 | Performance evaluation of in vitro diagnostic medical devices. |
| EN ISO 23640:2013 | In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents. |
| EN ISO 14971:2012 | Medical Devices – Application of risk management to medical devices. |
| EN ISO 18113-1:2011 | In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements. |
| EN ISO 18113-2:2011 | In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use. |

PZ CORMAY S.A Quality Management System complies with requirements of ISO 9001:2008 and EN ISO 13485:2012 standards and has been approved by Lloyd's Register Quality Assurance Limited in the range concerning design, production and distribution of in vitro diagnostic reagents for medical, industrial and scientific laboratories and design, production, sales and maintenance of in vitro diagnostic medical devices.



Nguyễn Ngọc Thành
 GIÁM ĐỐC
Nguyễn Ngọc Thành



Signature: *[Signature]*
 Janusz Plocica
 President of Management Board of
 PZ CORMAY S.A.


Signature: *[Signature]*
 Wojciech Suchowski
 Vice President of Management Board of
 PZ CORMAY S.A.

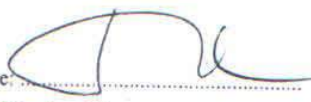
Place: Lomianki

Date: 31 May 2017

ATTACHMENT 1

No	Cat. No	Name
1	8-894	CLEANING REAGENT
2	8-525	CLEANING REAGENT NK
3	8-868	CLEANER
4	8-500	DILUENT
5	8-813	DILUENT
6	8-866	DILUENT
7	8-879	DILUENT
8	8-882	DILUENT
9	8-886	DILUENT
10	8-892	DILUENT
11	8-522	DILUENT NK
12	8-875	DILUENT PLUS
13	8-505	ENZYMATIC CLEANER
14	8-831	ENZYMATIC CLEANER
15	8-874	ENZYMATIC CLEANER
16	8-881	ENZYMATIC CLEANER
17	8-895	ENZYMATIC CLEANER FORTE
18	8-527	ENZYMATIC CLEANER NK
19	8-832	FLUSH
20	8-860	FLUSH
21	8-861	FLUSH
22	8-891	FLUSH
23	8-896	FLUSH SET
24	8-870	LYSING REAGENT
25	8-880	LYSING REAGENT
26	8-504	LYSING REAGENT BASO II
27	8-501	LYSING REAGENT CN FREE
28	8-502	LYSING REAGENT CN FREE
29	8-814	LYSING REAGENT CN FREE
30	8-883	LYSING REAGENT CN FREE
31	8-890	LYSING REAGENT CN FREE
32	8-893	LYSING REAGENT CN FREE
33	8-503	LYSING REAGENT EO
34	8-877	LYSING REAGENT KX21 CN FREE
35	8-884	LYSING REAGENT KX21 CN FREE
36	8-523	LYSING REAGENT NK 3
37	8-524	LYSING REAGENT NK 5
38	8-601	HAEM 8 CONTROL L

Signature: 
 Janusz Płocica
 President of Management Board of
 PZ CORMAY S.A.

Signature: 
 Wojciech Suchowski
 Vice President of Management Board of
 PZ CORMAY S.A.


Place: Lomianki

Date: 31 May 2017


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No	Cat. No	Name
39	8-602	HAEM 8 CONTROL N
40	8-603	HAEM 8 CONTROL H
41	8-604	HAEM 12 CONTROL L
42	8-605	HAEM 12 CONTROL N
43	8-606	HAEM 12 CONTROL H
44	8-607	HAEM K-DIFF CONTROL L
45	8-608	HAEM K-DIFF CONTROL N
46	8-609	HAEM K-DIFF CONTROL H

Signature: 
 Janusz Płocica
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