

ADVISORY NOTICE

19-2_2026_Delisting of non-IVDR products from portfolio

Dear customer,

We hereby inform you about transition from IVDD to IVDR – Discontinuation of Certain Products.

The European In Vitro Diagnostic Directive (IVDD 98/79/EC) is being replaced by the In Vitro Diagnostic Regulation (IVDR (EU) 2017/746). This transition introduces stricter requirements for placing in vitro diagnostic medical devices on the EU market.

Impact on Our Product Portfolio

Following a comprehensive portfolio review, Erba Lachema s.r.o. wishes to inform you:

- Certain products currently CE marked under IVDD will **not transition** to IVDR.
- These products will be **discontinued** and **production will cease no later than the applicable legal deadlines**:
 - **Class C devices** → latest until **26 May 2026**
 - **Class B devices** → latest until **26 May 2027**
- Please note: These dates represent the **latest legal deadlines**. In practice, **production of the affected IVDD products will stop earlier** as soon as their equivalent products are made available under IVDR.

After the above deadlines, IVDD products may no longer be placed on the EU market with the CE mark.

Continuation of Production under IVDR

- Products successfully transferred to IVDR will continue to be produced and CE marked in compliance with IVDR.
- The transition will be implemented on a **product-by-product basis**, which means that some IVDD versions may be discontinued earlier than the latest legal deadlines as soon as their IVDR counterparts are introduced.

Next Steps for Customers and Partners

We recommend you to:

1. Review your stock and forecast requirements for the affected IVDD products.
2. Place orders accordingly, keeping in mind the earlier possible discontinuation due to IVDR transition.
3. Contact your sale representative to discuss suitable IVDR alternatives.

In case you have any additional question, please do not hesitate to contact us.

Affected Products

Cat. number	Product name	Pack name	IVDR class	Replacement
BLT00002	ALBUMIN	ALB 500	B	BLT00001 ALB 250
BLT00008	ALPHA AMYLASE	AMY 500	C	BLT00007 AMY 250
XSYS0074	ALT/GPT	ALT/GPT 564 XL-1000	B	XSYS0017 ALT/GPT 330
XSYS0073	AST/GOT	AST/GOT 564 XL-1000	B	XSYS0016 AST/GOT 330
BLT00078	BILIRUBIN DIRECT DCA	BIL D DCA 500	C	XSYS0086 BIL D DCA 330
BLT00077	BILIRUBIN TOTAL DCA	BIL T DCA 500	B	XSYS0087 BIL T DCA 330
BLT00019	CREATININE	CREA 1000	B	AN 40/2025
BLT00021	CREATININE	CREA 500 S	B	AN 40/2025
XSYS0076	CREATININE	CREA 564 XL-1000	B	XSYS0024 CREA 275
XSYS0077	GAMMAGLUTAMYLTRANSFERASE	GGT 330 XL-1000	B	XSYS0011 GGT 110
BLT00026	GLUCOSE	GLU 4x250	C	BLT00025 GLU 500
BLT00027	GLUCOSE	GLU 1000	C	AN 15/2026
XSYS0069	GLUCOSE	GLU 576 XL-1000	C	XSYS0012 GLU 440
XSYS0078	HDL DIRECT	HDL C 360 XL-1000	B	XSYS0043 HDL C 160
BLT00032	HDL PREC	HDL PREC 100	B	BLT00028 HDL 80
BLT00033	CHLORIDE	CL 250	B	XSYS0008 CL 120
XSYS0070	CHOLESTEROL	CHOL 576 XL-1000	B	XSYS0009 CHOL 440
BLT00035	CHOLESTEROL	CHOL 1000	B	AN 15/2026
BLT00043	LDL CHOLESTEROL DIRECT	LDL C DIRECT 80	B	BLT00042 LDL C DIRECT 240
BLT00083	LEUCODIF	LEUCODIF 200	B	without replacement
BLT00047	PHOSPHORUS	PHOS 100	B	BLT00048 PHOS 250
XSYS0071	TRIGLYCERIDES	TG 576 XL-1000	B	XSYS0041 TG 440
BLT00058	TRIGLYCERIDES	TG 1000	B	AN 15/2026
XSYS0075	UREA	UREA 564 XL-1000	B	XSYS0020 UREA 275
XSYS0042	URIC ACID (SINGLE REAGENT)	UA 440	B	AN 40/2025
BLT00064	URIC ACID AOD	UA 500 S	B	AN 40/2025
BLT20004	ASO CONTROL	ASO CON	B	BLT20034 MULTICON L1, BLT20035 MULTICON L2
XSYS0094	C-REACTIVE PROTEIN	CRP 276 XL-1000	C	XSYS0047 CRP
BLT20029	LIPOPROTEIN (a)	Lp (a)	B	without replacement
BLT20030	MICROALBUMIN	MAL 10	B	XSYS0083 MAL
BLT20031	MICROALBUMIN	MAL 5	B	XSYS0083 MAL
URPH0020	MICROALBUPHAN	-	B	URPH0029 MICROALBUPHAN LAURA
URPH0021	Uro-dip 10e	-	B	URPH0028 DEKAPHAN LAURA
URPH0022	Uro-dip 2V GK	-	B	without replacement
URPH0023	Uro-dip 2V PG	-	B	without replacement

Cat. number	Product name	Pack name	IVDR class	Replacement
EHL00026	Erba Thrombin Time	Erba Thrombin Time 50	B	EHL00007 Erba Thrombin Time (10x 2 ml)
MLT00009	ENTERO-Screen	-	B	MLT00006 ENTEROtest 24
MLT00029	mCOLItest	-	B	MLT00030 OXItest (different design)
MLT00030	mOXItest	-	B	MLT00035 COLItest (different design)
MLT00054	MIC Cefuroxime	-	B	MLT00044 MIC G-I
MLT00056	MIC Clindamycin	-	B	MLT00043 MIC G+, MLT00047 MIC STAPHY
INS00066	ELite 3 (open system)	-	B	H360
INS00067	ELite 3 (closed system)	-	B	H360
INS00068	ELite 5	-	B	H560,H580
HEM00001	Erba Cleaner	-	B	without replacement
HEM00002	Erba Diff-5P	-	B	without replacement
HEM00003	Erba Dil-5P	-	B	without replacement
HEM00004	Erba Diluent-Diff	-	B	without replacement
HEM00005	Erba Hypoclean CC	-	B	without replacement
HEM00006	Erba Lyse-5P	-	B	without replacement
HEM00007	Erba Lyse-Diff (open system)	-	B	without replacement
HEM00008	Erba Lyse-Diff (closed system)	-	B	without replacement
HEM00009	ELite 5 HEM Control Low	-	B	without replacement
HEM00010	ELite 5 HEM Control Normal	-	B	without replacement
HEM00011	ELite 5 HEM Control High	-	B	without replacement
HEM00012	ELite HEM Calibrator	-	B	without replacement
HEM00013	ELite 3 HEM Control Low	-	B	without replacement
HEM00014	ELite 3 HEM Control Normal	-	B	without replacement
HEM00015	ELite 3 HEM Control High	-	B	without replacement
HEM00016	Erba Hypoclean	-	B	without replacement
INS00055	Hb 820	-	C	without replacement
REG00038	Hb-Vario Kit	-	C	without replacement
REG00039	Hb-Vario HbA1c Calibrator Set CM	-	C	without replacement
REG00040	Hb-Vario HbA1c Calibrator Set	-	C	without replacement
REG00041	Hb-Vario HbA1c Control Set	-	C	without replacement
REG00042	Hb-Vario Hemolyser Reagent	-	C	without replacement
REG00043	Hb-Vario Cleaner Solutions	-	C	without replacement
REG00044	Hb-Vario Complete Kit	-	C	without replacement
10003238	Multistandard SET	-	B	without replacement
10006876	IMMUNOGLOBULIN A ready-to-use	-	B	without replacement
10006877	IMMUNOGLOBULIN G ready-to-use	-	B	without replacement
10006878	IMMUNOGLOBULIN M ready-to-use	-	B	without replacement

Cat. number	Product name	Pack name	IVDR class	Replacement
10007746	COMPLEMENT C3 ready-to-use	-	C	without replacement
10007747	COMPLEMENT C4 ready-to-use	-	C	without replacement
10007748	TRANSFERIN ready-to-use	-	B	without replacement
10010248	CYSTATIN C	-	B	without replacement
10010249	CYSTATIN C Calibrator	-	B	without replacement
10010250	CYSTATIN C Control	-	B	without replacement

Best regards,

Erba Lachema s.r.o.



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