

Attachment 1- List of affected products

Table 1 : List of affected product references

Product Ref.	Product name	GMDN code	GMDN Nomenclature	UDI	EU classification
30118	VIDAS® C. difficile Toxin A & B	50832	Clostridium difficile toxin A/B antigen IVD, kit, enzyme immunoassay (EIA)	03573026064204	D - Except Annex II
30118-01				03573026229146	N/A
30125	VIDAS® C. difficile GDH	50824	Clostridium difficile antigen IVD, antibody	03573026334819	D - Except Annex II
30125-01				03573026444204	N/A
30211	VIDAS® TOXO Compétition	52444	Toxoplasma gondii total antibody IVD, kit, enzyme immunoassay (EIA)	03573026064457	B - Annex II List B
30308	VIDAS® Anti-HCV	48359	Hepatitis C virus immunoglobulin G (IgG) antibody IVD, kit, enzyme immunoassay (EIA)	03573026351274	A - Annex II List A
30314	VIDAS® Anti-HBc Total II	48303	Hepatitis B virus core total antibody IVD, kit, enzyme immunoassay (EIA)	03573026064815	A - Annex II List A
30315	VIDAS® HBs Ag Ultra	48319	Hepatitis B virus surface antigen IVD, kit, enzyme immunoassay (EIA)	03573026064822	A - Annex II List A
30318	VIDAS® Anti-HBs Total II	48315	Hepatitis B virus surface total antibody IVD, kit, enzyme immunoassay (EIA)	03573026064853	A - Annex II List A
30405	VIDAS® HCG	54210	Total human chorionic gonadotropin (HCG) IVD, kit, enzyme immunoassay (EIA)	03573026064914	D - Except Annex II
30409	VIDAS® Progesterone	54324	Progesterone IVD, kit, enzyme immunoassay (EIA)	03573026064952	D - Except Annex II
30409-01				03573026156954	N/A
30421	VIDAS® CK-MB	47385	See attachment 1	03573026065072	D - Except Annex II
30439	VIDAS® HBc IgM II	48297	Hepatitis B virus core immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	03573026065249	A - Annex II List A
30443	VIDAS® HIV DUO Ultra	48445	HIV1/HIV2 antigen/antibody IVD, kit, enzyme immunoassay (EIA)	03573026065287	A - Annex II List A

30446	VIDAS® Myoglobin	53953	Myoglobin IVD, kit, enzyme immunoassay (EIA)	03573026065317	D - Except Annex II
30447	VIDAS® HIV DUO Quick	48445	HIV1/HIV2 antigen/antibody IVD, kit, enzyme immunoassay (EIA)	03573026119812	A - Annex II List A
30450	VIDAS® B•R•A•H•M•S PCT™	61534	Procalcitonin (PCT) IVD, kit, enzyme immunoassay (EIA)	03573026129392	D - Except Annex II
30450-01				03573026223601	N/A
30450-30				03573026620882	N/A
30450-86				03573026557089	D - Except Annex II
30455	VIDAS® D-Dimer Exclusion II™	47345	D-dimer IVD, kit, enzyme immunoassay (EIA)	03573026223564	D - Except Annex II
30455-01				03573026387006	N/A
30455-02				03573026560799	D - Except Annex II
30455-30				03573026620899	
30458	VIDAS® NT-proBNP2	47350	B-type natriuretic protein/N-terminal pro b-type natriuretic peptide IVD, kit, enzyme immunoassay (EIA)	03573026229641	D - Except Annex II
30458-30				03573026620905	
30603	VIDAS® Digoxin	55324	Digoxin therapeutic drug monitoring IVD, kit, enzyme immunoassay (EIA)	03573026065690	D - Except Annex II
415386	VIDAS® High sensitive Troponin I	54009	Troponin I IVD, kit, enzyme immunoassay (EIA)	03573026433147	D - Except Annex II
415386-30				03573026620929	
418115	VIDAS® Anti-HEV IgM	48411	Hepatitis E virus immunoglobulin M (IgM) antibody IVD, kit, enzyme immunoassay (EIA)	03573026467319	D - Except Annex II
421172-03	VIDAS® NEPHROCHEC K®	60639	Multiple acute kidney injury (AKI) marker IVD, kit, fluorescent immunoassay	03573026617387	D - Except Annex II
423077	VIDAS® DENGUE NS1 Ag	48907	Dengue virus antigen IVD, kit, enzyme immunoassay (EIA)	03573026608217	D - Except Annex II
423078	VIDAS® Anti-DENGUE IgM	48936	Dengue virus immunoglobulin A (IgA)/IgG/IgM antibody IVD, kit, enzyme immunoassay (EIA)	03573026608224	D - Except Annex II

Table 2 : List of impacted lots of clinical VIDAS® Immuno-assays per product reference

SYSTEM	Product reference	Product name	Lot	Current expiry date	Revised expiry date
VIDAS® C.DIFFICILE TOXIN A&B	30118	VIDAS CD A.B 60 TESTS	1008926680	08/07/2022	01/06/2022
			1008731010	09/04/2022	10/03/2022
	30118-01	VIDAS C.DIFFICILE TOXIN A/B 60T	1008730880	09/04/2022	10/03/2022
VIDAS® C DIFFICILE GDH	30125	VIDAS GDH 60 TESTS	1008597480	18/04/2022	25/01/2022
			1008686700	06/06/2022	03/03/2022
			1008859220	03/09/2022	13/06/2022
	30125-01	VIDAS C DIFFICILE GDH 60 TESTS	1008686690	06/06/2022	03/03/2022
VIDAS® TOXO COMPETITION	30211	VIDAS TOXO COMPETITION 60 TEST	1008615860	24/02/2022	09/02/2022
			1008864170	28/06/2022	08/06/2022
VIDAS® ANTI-HCV	30308	VIDAS ANTI-HCV 60 TESTS	1008624280	30/05/2022	26/01/2022
			1008837640	14/09/2022	26/05/2022
			1008722870	20/07/2022	25/03/2022
			1008808970	09/09/2022	17/05/2022
			1008857200	01/10/2022	16/06/2022
			1008860610	01/10/2022	16/06/2022
VIDAS® ANTI-HBC TOTAL II	30314	VIDAS ANTI-HBC TOTAL II 60TEST	1008654830	11/03/2022	23/02/2022
VIDAS® HBS AG ULTRA	30315	VIDAS HBS AG ULTRA 60 TESTS	1008612250	26/03/2022	25/01/2022
			1008614380	26/03/2022	25/01/2022
			1008642570	22/04/2022	23/02/2022
			1008735620	26/05/2022	07/04/2022
			1008790310	05/07/2022	17/05/2022
			1008790410	05/07/2022	17/05/2022
			1008861610	06/08/2022	16/06/2022
VIDAS® ANTI HBS TOTAL II	30318	VIDAS ANTI HBS TOTAL II 60T	1008719940	29/07/2022	30/11/2021
			1008830740	07/10/2022	18/01/2022
			1008865350	03/11/2022	06/02/2022
VIDAS® HCG	30405	VIDAS HCG 60 TESTS	1008714630	26/04/2022	27/11/2021
			1008747680	11/05/2022	27/11/2022
			1008757640	18/05/2022	19/12/2021
			1008784120	03/06/2022	01/01/2022
			1008796930	02/06/2022	09/01/2022
			1008808600	14/06/2022	09/01/2022
			1008824160	17/06/2022	25/01/2022
			1008827550	16/06/2022	25/01/2022
			1008849560	01/07/2022	05/02/2022
			1008861770	08/07/2022	05/02/2022
			1008881760	15/07/2022	15/02/2022
			1008920140	06/08/2022	27/02/2022
			1008924590	05/08/2022	22/03/2022
			1008926200	18/08/2022	22/03/2022
VIDAS® PROGESTERONE	30409	VIDAS PROGESTERONE 60 TESTS	1008615920	02/03/2022	03/02/2022
			1008685480	20/05/2022	07/04/2022

			1008686900	13/04/2022	22/03/2022
			1008730710	29/04/2022	04/04/2022
			1008775650	28/05/2022	09/05/2022
			1008816010	10/06/2022	09/05/2022
			1008816030	10/06/2022	09/05/2022
			1008873190	08/07/2022	23/06/2022
			1008911230	06/08/2022	05/07/2022
	30409-01	VIDAS PROGESTERONE 60 TESTS	1008685490	13/04/2022	22/03/2022
			1008766980	29/04/2022	04/04/2022
			1008775630	28/05/2022	09/05/2022
			1008873180	08/07/2022	23/06/2022
			1008911240	06/08/2022	05/07/2022
VIDAS® CK MB	30421	VIDAS CK MB 30 TESTS	1008557760	21/01/2022	12/01/2022
			1008934620	15/07/2022	29/06/2022
VIDAS® HBC IGM II	30439	VIDAS HBC IGM II 30 TESTS	1008636760	12/03/2022	23/02/2022
			1008888750	29/06/2022	08/06/2022
VIDAS® HIV DUO ULTRA	30443	VIDAS HIV DUO ULTRA 60 TESTS	1008675340	30/03/2022	13/09/2021
			1008745740	27/04/2022	18/10/2021
			1008829020	29/06/2022	19/12/2021
			1008834410	21/06/2022	06/12/2021
VIDAS® MYOGLOBIN	30446	VIDAS MYOGLOBIN 30 TESTS	1008658660	23/03/2022	26/10/2021
			1008708120	22/04/2022	14/11/2021
			1008802100	08/06/2022	01/01/2022
			1008813810	08/06/2022	01/01/2022
VIDAS® HIV DUO QUICK	30447	VIDAS HIV DUO QUICK 60 TESTS	1008680850	11/04/2022	02/10/2021
			1008592410	31/01/2022	07/08/2021
			1008802860	13/06/2022	27/11/2021
VIDAS® BRAHMS PROCALCITONIN 60 TESTS	30450	VIDAS BRAHMS PROCALCITONIN 60 TESTS	1008661450	21/09/2022	26/10/2021
			1008591130	15/08/2022	20/09/2021
			1008633310	08/09/2022	28/09/2021
			1008641870	08/09/2022	28/09/2021
			1008722440	27/10/2022	30/11/2021
			1008741790	07/11/2022	30/11/2021
			1008769030	24/11/2022	31/12/2021
			1008784200	30/11/2022	09/01/2022
			1008796890	11/12/2022	31/12/2021
			1008817120	15/12/2022	24/01/2022
			1008886330	18/01/2023	08/02/2022
			1008926040	08/02/2023	21/03/2022
	30450-01	VIDAS BRAHMS PROCALCITONIN 60T	1008603580	22/08/2022	20/09/2021
			1008748010	14/11/2022	30/11/2021
			1008888030	19/01/2023	12/02/2022
			1008584190	10/08/2022	19/09/2021
			1008647850	14/09/2022	18/10/2021
			1008903210	31/01/2023	21/02/2022
			1008926050	08/02/2023	21/03/2022

	30450-30	VIDAS® BRAHMS PROCALCITONIN 30T	1008741800	07/11/2022	30/11/2021
			1008926060	08/02/2023	21/03/2022
	30450-86	VIDAS® BRAHMS PROCALCITONIN 60T	1008562400	13/07/2022	06/09/2021
			1008594750	21/08/2022	20/09/2021
			1008784190	30/11/2022	09/01/2022
			1008817140	15/12/2022	24/01/2022
			1008671350	29/09/2022	26/10/2021
			1008714950	24/10/2022	30/11/2021
			1008741810	07/11/2022	30/11/2021
			1008769290	24/11/2022	31/12/2021
			1008868260	12/01/2023	12/02/2022
			1008888040	19/01/2023	12/02/2022
			1008892830	19/01/2023	12/02/2022
			1008903360	31/01/2023	21/02/2022
VIDAS® D DIMER EXCLUSION II	30455	VIDAS® D DIMER EXCLUSION II 60T	1008589450	17/02/2022	25/01/2022
			1008815230	13/06/2022	17/05/2022
			1008761040	22/05/2022	28/04/2022
			1008770900	31/05/2022	04/05/2022
			1008778210	30/05/2022	28/04/2022
			1008800130	03/06/2022	08/05/2022
	30455-01	VIDAS® D DIMER EXCLUSION II 60T US	1008815200	14/06/2022	27/05/2022
			1008696660	13/04/2022	22/03/2022
			1008761020	22/05/2022	28/04/2022
			1008864290	15/07/2022	16/06/2022
	30455-02	VIDAS® D-DIMER EXCLUSION II 60T	1008891690	27/07/2022	29/06/2022
			1008656010	23/03/2022	03/03/2022
			1008696080	13/04/2022	22/03/2022
			1008705690	18/04/2022	07/04/2022
			1008589420	16/02/2022	26/01/2022
			1008592150	23/02/2022	03/02/2022
			1008609020	26/02/2022	03/02/2022
			1008720080	18/04/2022	07/04/2022
			1008732940	04/05/2022	19/04/2022
			1008744900	07/05/2022	19/04/2022
			1008756000	17/05/2022	04/05/2022
			1008761030	22/05/2022	28/04/2022
			1008762030	25/05/2022	28/04/2022
			1008763980	24/05/2022	04/05/2022
			1008771100	31/05/2022	04/05/2022
			1008778230	30/05/2022	28/04/2022
			1008781240	03/06/2022	08/05/2022
			1008815220	14/06/2022	27/05/2022
			1008815240	13/06/2022	17/05/2022
			1008864310	15/07/2022	16/06/2022
			1008891770	27/07/2022	29/06/2022
			1008917580	17/08/2022	27/07/2022

	30455-30	VIDAS® D-DIMER EXCLUSION II 30T	1008918050	31/05/2022	04/05/2022
			1008918060	03/06/2022	08/05/2022
			1008589440	16/02/2022	26/01/2022
			1008660630	23/03/2022	03/03/2022
			1008705360	13/04/2022	22/03/2022
			1008732910	04/05/2022	19/04/2022
			1008763990	24/05/2022	04/05/2022
			1008891780	27/07/2022	29/06/2022
			1008864300	15/07/2022	16/06/2022
VIDAS® NT-PROBNP 2	30458	VIDAS® NT-PROBNP 2 60 TESTS	1008693930	15/04/2022	13/09/2021
			1008747590	04/05/2022	11/10/2021
			1008776240	01/06/2022	26/10/2021
			1008838180	30/06/2022	17/11/2021
			1008851520	30/06/2022	17/11/2021
			1008886400	20/07/2022	22/12/2021
			1008894100	27/07/2022	04/01/2022
			1008894140	27/07/2022	04/01/2022
	30458-30	VIDAS® NT-PROBNP 2 30 TESTS	1008699310	15/04/2022	13/09/2021
			1008776230	01/06/2022	26/10/2021
			1008897360	27/07/2022	04/01/2022
VIDAS® DIGOXIN - DIG	30603	VIDAS® DIGOXIN - DIG 60 TESTS	1008824700	22/06/2022	27/05/2022
VIDAS® HIGH SENSITIVE TROPONIN I	415386	VIDAS® HIGH SENSITIVE TROPONIN I 60 TESTS	1008694760	06/07/2022	13/09/2021
			1008727610	29/07/2022	29/09/2021
			1008666230	19/06/2022	25/08/2021
			1008576310	08/05/2022	06/07/2021
			1008903780	29/10/2022	04/01/2022
			1008677520	01/07/2022	25/08/2021
			1008752990	11/08/2022	11/10/2021
			1008768930	24/08/2022	26/10/2021
			1008768940	21/08/2022	30/10/2021
			1008801930	02/09/2022	08/11/2021
			1008809020	10/09/2022	08/11/2021
			1008827440	17/09/2022	18/11/2021
			1008829290	16/09/2022	08/11/2021
			1008843450	23/09/2022	18/11/2021
			1008848240	30/09/2022	30/11/2021
			1008848270	30/09/2022	30/11/2021
			1008867160	09/10/2022	12/12/2021
			1008867170	09/10/2022	12/12/2021
			1008872350	08/10/2022	08/12/2021
			1008882110	15/10/2022	06/12/2021
			1008886390	19/10/2022	06/12/2021
			1008890790	18/10/2022	08/12/2021
			1008893760	26/10/2022	22/12/2021
			1008901930	28/10/2022	22/12/2021
			1008912850	04/11/2022	04/01/2022

	415386-30	VIDAS® HS TROPONIN I 30 TESTS	1008912800	04/11/2022	04/01/2022
VIDAS® HEV IGM	418115	VIDAS® HEV IGM 30T	1008652560	19/09/2022	23/02/2022
			1008776540	28/11/2022	28/04/2022
			1008868900	16/01/2023	14/06/2022
VIDAS® NEPHROCHECK	421172-03	VIDAS® NEPHROCHECK 30 TESTS	1008838860	22/09/2022	26/05/2022
VIDAS® DENGUE NS1 AG	423077	VIDAS® DENGUE NS1 AG 60T	1008731920	26/10/2022	07/04/2022
			1008785470	29/11/2022	08/05/2022
			1008899350	03/01/2023	08/06/2022
VIDAS® ANTI DENGUE IGM	423078	VIDAS® ANTI DENGUE IGM 60T	1008730620	17/10/2022	07/04/2022
			1008781310	27/11/2022	28/04/2022
			1008921610	29/01/2023	30/06/2022