



**DEKLARACJA ZGODNOŚCI UE/
EU DECLARATION OF CONFORMITY**



DANE DOTYCZĄCE PRODUCENTA / MANUFACTURER DETAILS	
Producent / Manufacturer	Graso Zenon Sobiecki
Adres producenta / Address	Krąg 4A 83-200 Starogard Gdański
Numer rejestracyjny producenta / Manufacturer's registration number	PL-MF-000022437
DANE DOTYCZĄCE WYROBU / DEVICE DETAILS	
Nazwa produktu / Product name	Patrz załączona lista produktów poniżej (Tabela 1). See attached product list below (Table 1).
Numer katalogowy / Article number	Patrz załączona lista produktów poniżej (Tabela 1). See attached product list below (Table 1).
Basic UDI-DI	Patrz załączona lista produktów poniżej (Tabela 1). See attached product list below (Table 1).
Klasa ryzyka wyrobu, wg reguły / Risk class and classification rule	klasa A wg Załącznika VIII reguła 5a / class A acc. Annex VIII rule 5a
Ocena zgodności/ Conformity assessment	wg Załącznika IX acc. to Annex IX
OŚWIADCZENIE PRODUCENTA / MANUFACTURER STATEMENT	
<p>Producent Graso Zenon Sobiecki z siedzibą firmy w miejscowości Krąg 4A, 83-200 Starogard Gdański na swoją wyłączną odpowiedzialność oświadcza, że:</p> <p>wyżej wymienione produkty spełniają wymagania Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/746 z 5 kwietnia 2017r. w sprawie wyrobów medycznych do diagnostyki in vitro oraz uchylenia dyrektywy 98/79/WE i decyzji Komisji 2010/227/UE oraz wymagania Ustawy o wyrobach medycznych z dnia 7 kwietnia 2022 r. Dokumentacja techniczna potwierdzająca zgodność wyrobu z powyższymi wymaganiami przechowywana jest w siedzibie producenta./</p> <p>The manufacturer Graso Zenon Sobiecki located in Krąg 4A, 83-200 Starogard Gdański declares on his own responsibility that:</p> <p>the above-mentioned products meet the requirements of the Regulation of the European Parliament and of the Council (EU) 2017/746 of April 5, 2017. on in vitro diagnostic medical devices and repealing Directive 98/79 / EC and Commission Decision 2010/227/ EU and the requirements of the Medical Devices Act of April 7, 2022. . The technical</p>	

documentation confirming the compliance of the product with the requirements of the Regulation is kept at the manufacturer's premises.

ZASTOSOWANE WSPÓLNE SPECYFIKACJE, Z KTÓRYMI DEKLARUJE SIĘ ZGODNOŚĆ /

REFERENCES TO ANY COMMON SPECIFICATION USED AND IN RELATION TO WHICH CONFORMITY IS DECLARED

Producent posiada zintegrowany System Zarządzania Jakością zgodny z:

The manufacturer implemented integrated quality management system in accordance with:

PN-EN ISO 9001 Systemy Zarządzania Jakością. Wymagania. / Quality Management System. Requirements.

PN-EN ISO 13485 Wyroby medyczne. Systemy zarządzania jakością. Wymagania do celów przepisów prawnych. / Medical devices. Quality management systems. Requirements for regulatory purposes.

DATA I MIEJSCE WYDANIA DEKLARACJI ZGODNOŚCI /

PLACE AND DATE OF ISSUE OF THE DECLARATION OF CONFORMITY

04.12.2023r. Krąg 4A, 83-200 Starogard Gdański

Tabela 1. Lista produktów objętych powyższą deklaracją zgodności. /

Table 1. The list of products covered by above declaration of conformity.

Numer katalogowy / Article number	Nazwa produktu / Product name	Basic UDI-DI
1000BT25	Sheep Blood Defibrinated	590470800DCZYNNIKTE
1000BT50		
1000BT100		
1000BT200		
1000BT500		
1005PD90	Clostridioides Difficile Agar	590470801005PD90L9
1007PD90	CHROMagar StrepB	590470801007PD90LX
1010PD90	Willis Hobbs Agar	590470801010PD90JX
1011PD90	Levine Eosin Methylene Blue Agar (LEMB Agar)	590470801011PD90KA
1016PD90	Burkholderia Cepacia Agar	590470801016PD90LZ
1020PD90	MacConkey Agar + Crystal Violet	590470801020PD90KC
1021PD90	MacConkey Agar + Sorbitol	590470801021PD90KP
1026PD90	MacConkey CS Agar	590470801026PD90ME
1030PD90	CLED Agar	590470801030PD90KR
1033PD90	Brucella Agar + 5% Horse Blood	590470801033PD90LS
1039PD90	Bacterioides Bile Esculin Agar (BBE)	590470801039PD90NU
1040PD90	Bismuth Sulphite Agar (Wilson Blair)	590470801040PD90L6
1041PD90	Wilkins Chalgren Agar + Vancomycin + Nalidixic Acid	590470801041PD90LH
1043PD90	Brucella Agar + 5% Sheep Blood + Supplements	590470801043PD90M7
1050PD90	Mannitol Salt Agar	590470801050PD90LK
1060PD90	Hektoen Enteric Agar	590470801060PD90LY
1070PD90	Enterococcosel Agar	590470801070PD90MD
1080PD90	Chocolate Agar	590470801080PD90MS
1090PD90	Yersinia CIN Agar	590470801090PD90N7
1110PD90	Blood Agar	590470801110PD90KG
1112PD90	Azide Blood Agar + Crystal Violet	590470801112PD90L6
1123PD90	Columbia CAP Agar + 5% Sheep Blood	590470801123PD90LW
1124PD90	Drigalski Agar	590470801124PD90M9
1162PD90	Brain Heart Infusion Agar+ Vancomycin (BHI Agar + Vancomycin)	590470801162PD90N7
1166PD90	Nutrient Agar	590470801166PD90PK
1168PD90	Brain Heart Infusion Agar (BHI Agar)	590470801168PD90Q9

1181PD90	Tryptic Soy Agar + 5% Sheep Blood (TSA + 5% Sheep Blood)	590470801181PD90NN
1186PD90	Brain Heart Infusion Agar + Potassium Tellurite (BHI Agar + Potassium Tellurite)	590470801186PD90QD
1190PD90	Columbia Agar + 5% Sheep Blood	590470801190PD90NQ
1190PD140		
1190BPD90	Columbia Agar z 7% Sheep Blood	59047080PODŁOZAWZROPDVR
1191PD90	Columbia CNA + 5% Sheep Blood	590470801191PD90P3
1196PD90	Columbia Agar+ 5% Horse Blood	590470801196PD90QS
1200PD90	Schaedler Agar + 5% Sheep Blood	590470801200PD90KL
1201PD90	Schaedler Agar + 5% Sheep Blood + Vit. K3	590470801201PD90KX
1202PD90	Schaedler CNA Agar + 5% Sheep Blood	590470801202PD90LA
1204PD90	Wilkins Chalgren Agar + 5% Sheep Blood	590470801204PD90LY
1205PD90	Schaedler NeoVanco Agar + 5% Sheep Blood	590470801205PD90MB
1207PD90	Schaedler KanaVanco Agar + 5% Sheep Blood	590470801207PD90MZ
1230PD90	Sabouraud Dextrose Agar	590470801230PD90LT
1231PD90	Sabouraud Dextrose Agar + Chloramphenicol	590470801231PD90M6
1232PD90	Sabouraud Dextrose Agar +Chloramphenicol + Gentamycin	590470801232PD90MH
1232PD60		
1233PD90	Sabouraud Dextrose Agar +Chloramphenicol + Actidione	590470801233PD90MU
1234PD90	Sabouraud Dextrose Agar + Actidione	590470801234PD90N7
1240PD90	Fungisel Agar	590470801240PD90M8
1250PD90	Salmonella Shigella Agar	590470801250PD90MM
1261PD90	Haemophilus Chocolate Agar	590470801261PD90ND
1291PD90	Campylobacter Agar + 10% Sheep Blood	590470801291PD90PL
1310PD90	Cetrymide Agar	590470801310PD90LJ
1330PD90	XLD Agar	590470801330PD90MC
1381PD90	CHROMagar STEC	590470801381PD90PQ
1385PD90	CHROMagar Campylobacter	590470801385PD90R4
1400PD90	CHROMagar Candida	590470801400PD90LN
1402PD90	CHROMagar MRSA	590470801402PD90MC
1404PD90	CHROMagar Staph aureus	590470801404PD90N2
1406PD90	CHROMagar Candida Plus	59047080PODŁOZAWZRSPDWD
1407PD90	CHROMagar Malassezia	59047080PODŁOZAWZRSPDWD
1408PD90	CHROMagar C. difficile	590470801408PD90PE
1410PD90	CHROMagar Orientation	590470801410PD90M3
1411PD90	Diff Colour Agar	590470801411PD90ME
1421PD90	CHROMagar Salmonella Plus	59047080PODŁOZAWZRSPDWD

1421BPD90		
1450PD90	DNase Test Agar	590470801450PD90NP
1452PD90	Dermatophyte Test Agar (Derma TEST Agar)	590470801452PD90PD
1460PD90	CHROMagar VRE	590470801460PD90P4
1470PD90	CHROMagar ESB	590470801470PD90PH
1471PD90	CHROMagar KPC	590470801471PD90PU
1473PD90	CHROMagar mSuperCARBA	590470801473PD90QJ
1475PD90	CHROMagar COL-APSE	590470801475PD90R8
1481PD90	CHROMagar Acinetobacter	590470801481PD90Q9
1482PD90	CHROMagar Acinetobacter MDR	590470801482PD90QL
1484PD90	CHROMagar Y. enterocolitica	590470801484PD90RA
2001PD90	Columbia Agar + 5% Sheep Blood / Columbia Agar + 5% Sheep Blood	590470802001PD90KG
2014PD90	Salmonella Shigella Agar / Hektoen Enteric Agar	590470802014PD90LW
2017PD90	Sabouraud Dextrose Agar + Chloramphenicol / Fungisel Agar	590470802017PD90MX
2019PD90	CHROMagar VRE / CHROMagar KPC	590470802019PD90NM
2020PD90	MacConkey Agar + Crystal Violet / Sabouraud Dextrose Agar + Chloramphenicol + Gentamycin	590470802020PD90KX
2021PD90	Schaedler Agar + 5% Sheep Blood / Schaedler KanaVanco Agar + 5% Sheep Blood	590470802021PD90LA
2022PD90	Columbia CNA Agar + 5% Sheep Blood / Enterococcosel Agar	590470802022PD90LM
2024PD90	CHROMagar Candida / Sabouraud Dextrose Agar + Chloramphenicol + Gentamycin	590470802024PD90LOZAWZRSBPD9U
2025PD90	Salmonella Shigella Agar / XLD Agar	590470802025PD90MN
2029PD90	Wilkins Chalgren Agar + 5% Sheep Blood / Wilkins Chalgren Agar + 5% Sheep Blood	590470802029PD90P2
2030PD90	Sabouraud Dextrose Agar / CHROMagar Candida	590470802030PD90LC
2033PD90	CHROMagar VRE / CHROMagar MRSA	590470802033PD90MD
2036PD90	Columbia CNA Agar + 5% Sheep Blood / CHROMagar Candida	590470802036PD90NE
2037PD90	Salmonella Shigella Agar / Bismuth Sulphite Agar (Wilson Blair)	590470802037PD90NR

2040PD90	MacConkey Agar + Crystal Violet/ Columbia Agar + 5% Sheep Blood	590470802040PD90LR
2041PD90	Burkholderia Cepacia Agar / Pseudomonas CN Agar	590470802041PD90M4
2044PD90	CHROMagar Orientation / Columbia CNA Agar + 5% Sheep Blood	590470802044PD90N5
2047PD90	Columbia Agar + 5% Sheep Blood / Sabouraud Dextrose Agar + Chloramphenicol	590470802047PD90P6
2048PD90	CHROMagar Staph aureus / CHROMagar MRSA	590470802048PD90PH
2050PD90	MacConkey Agar + Crystal Violet / Columbia CNA Agar + 5% Sheep Blood	590470802050PD90M6
2051PD90	Sabouraud Dextrose Agar + Chloramphenicol / Sabouraud Dextrose Agar + Actidione	590470802051PD90MH
2052PD90	Columbia CNA Agar + 5% Sheep Blood / Haemophilus Chocolate Agar	590470802052PD90MU
2057PD90	CHROMagar ESBL / CHROMagar VRE	590470802057PD90PK
2061PD90	Columbia Agar + 5% Sheep Blood / Chocolate Agar	590470802061PD90MW
2066PD90	CHROMagar ESBL / CHROMagar mSuperCARBA	590470802066PD90PM
2068PD90	CHROMagar ESBL / CHROMagar KPC	590470802068PD90QB
2073PD90	CHROMagar Salmonella Plus / Hectoen Enteric Agar	590470802073PD90NZ
2081PD90	CHROMagar StrepB / Columbia CNA Agar + 5% Sheep Blood	590470802081PD90NQ
2086PD90	Columbia Agar + 5% Sheep Blood / Haemophilus Chocolate Agar	590470802086PD90QF
2096PD90	MacConkey Agar + Crystal Violet / CHROMagar Candida	590470802096PD90QU
2100PD90	Mac Conkey Agar + Crystal Violet / Blood Agar + 5% Sheep Blood	590470802100PD90KN
2111PD90	CHROMagar Orientation / Columbia Agar + 5% Sheep Blood	590470802111PD90LE
2118PD90	Columbia CAP Agar + 5% Sheep Blood / CHROMagar Candida	590470802118PD90NT
2120PD90	Columbia CAP Agar + 5% Sheep Blood / CHROMagar Orientation	590470802120PD90LG
2122PD90	Columbia CAP Agar + 5% Sheep Blood / Haemophilus Chocolate Agar	590470802122PD90M6
2134PD90	CHROMagar Salmonella Plus / Salmonella Shigella Agar	590470802134PD90N9

3010BT100	Sabouraud Dextrose Agar	590470803010BT100KZ
3010BT200		
3010BT500		
3012BT100	Enterococcosel Agar	590470803012BT100LT
3012BT200		
3012BT500		
3014BT100	Columbia Agar Base	590470803014BT100MM
3014BT100(KG)		
3014BT200		
3014BT500		
3016BT100	Mannitol Salt Agar	590470803016BT100NF
3016BT200		
3016BT500		
3017BT100	MacConkey Agar + Crystal Violet	590470803017BT100NU
3017BT200		
3017BT500		
3018BT100	Salmonella Shigella Agar	590470803018BT100P9
3018BT200		
3018BT500		
3019BT100	Chocolate Agar Base	590470803019BT100PN
3020BT100	Sabouraud Dextrose Agar + Chloramphenicol	590470803020BT100LJ
3020BT200		
3020BT200(KG)		
3020BT250		
3020BT500	Hektoen Enteric Agar	590470803021BT100LX
3021BT100		
3021BT200		
3021BT500		
3022BT100	Brain Heart Infusion Broth (BHI Broth)	590470803022BT100MC
3022BT200		
3022ABT200		
3022BT500		
3022VL30	Brain Heart Infusion Agar (BHI Agar)	590470803023BT100MR
3023BT100		
3023BT200		
3023BT500		
203023		
203023F1	Brucella Broth	59047080PODŁOZAWZROBTA96
3027BT100		
3032BT100	Tryptic Soy Broth (TSB)	590470803032BT100MV
3032BT200		
3032BT200(KG)		
3032BT250		

3032BT500		
3033BT100	Levine Eosin Methylene Blue Agar (LEMB Agar)	590470803033BT100NA
3033BT200		
3036BT100	Schaedler Agar Base + Vit.K	590470803036BT100PH
3036BT200		
3036BT500		
3037BT100	Selenite F Broth	590470803037BT100PW
3037BT200		
3037BT200(KG)		
3037BT500		
203037F5		
3040BT100	Sabouraud Dextrose Agar + Chloramphenicol + Actidion	590470803040BT100ML
3040BT200		
3040BT250		
3040BT500		
3041BT100	Todd-Hewitt Broth	590470803041BT100MZ
3041BT200		
3041BT200(KG)		
3041BT500		
3044BT200	Selenite Cysteine Broth	590470803044BT100P8
3044BT500		
203044F1		
3050BT100	Sabourad Dextrose Broth	590470803050BT100N5
3050BT200		
3050BT500		
3052BT100	EDTA	590470803052BT100NX
3052BT50		
3111BT100	Kligler Iron Agar	590470803111BT100LZ
3111BT200		
3111BT500		
3112BT100	Simmons Citrate Agar	590470803112BT100ME
3112BT200		
3114BT100	Maloniate Broth	590470803114BT100N8
3114BT100(KG)		
3114BT200		
3114BT200		
3114BT500		
3115BT100	Phenylalanine Agar	590470803115BT100NM
3115BT200		
3115BT250		
3116BT100	Christensen Broth	590470803116BT100P2
3116BT100(KG)		
3116BT200		

3116BT500		
3117BT100	1% Peptone Water + Tryptophane	590470803117BT100PF
3117BT100(KG)		
3117BT200		
3117BT500		
3118BT100	1% Glucose Broth	590470803118BT100PU
3118BT200		
3118BT500		
3119BT100	Indole - Urease Medium	590470803119BT100Q9
3119BT200		
3119BT500		
3120BT100	Standard Broth	590470803120BT100M5
3120BT200		
3120BT500		
3121BT100	6,5% Sodium Chloride Broth	590470803121BT100MJ
3121BT200		
3122BT100	Falkow Decarboxylase Broth +Lysine	590470803122BT100MX
3122BT100(KG)		
3122BT200		
3122BT500		
3123BT100	Falkow Decarboxylase Broth + Arginine	590470803123BT100NC
3123BT200		
3124BT100	Falkow Decarboxylase Broth + Ornithine	590470803124BT100NR
3124BT200		
3124BT500		
3125BT100	Bromocresol Purple Broth + 10% Lactose	590470803125BT100P6
3125BT100(KG)		
3125BT200		
3125BT500		
3128BT500	MacConkey Broth	590470803128BT100QD
3153BT50	Phenylboronic Acid	590470803153BT100PX
3208BT100	CHROMagar Candida	590470803208BT100PW
3208BT200		
3208BT500		
3217BT100	Garda Agar	59047080PODŁOZAWZRSBTAA2
3217BT200		
3514BT100	XLD Agar	59047080PODŁOZAWZRSBTAA2
3515BT100	Yersinia CIN Agar	590470803515BT100QZ
3515BT200		
3515SBT100		
3556BT100	CHROMagar Salmonella Plus	59047080PODŁOZAWZRSBTAA2
3556BT200		

3556BT500		
3583BT100		
3583BT200	0,85% NaCl Solution	590470803583BT100TW
3583BT500		
4014PD150	Brucella Agar + 5% Sheep Blood + Supplements	59047080PODŁOZAWZROPDVR
5011TB1	Viral Transport Medium (VTM)	590470805011TBUJ
5011TB3		
205011S1		
205011S3		
5011TB3WS1010		
5011WS1010		
5012TB1	Phosphate Buffered Saline (PBS)	59047080ODCZYNNIKTE
5012TB3		
6008TB7	Dermatophyte Test Agar (Derma Test Agar)	59047080PODŁOZAWZROTBAAA
6010TB5	Sabouroud Dextrose Broth	590470806010TBUS
6010TB10S		
6010TB10		
6010TB1		
6010TB5S		
6015TB7	Storage Agar (Agarek amerykański)	590470806015TBVK
6015TB5		
6015TB1		
6015TB3		
6015TB1,5		
6016TB1	Pneumococcal Broth	590470806016TBVQ
6016TB3		
6017TB1	Chocolate Agar	59047080PODŁOZAWZROTBAAA
6017TB3		
6020TB5	Brain Heart Infusion Broth (BHI Broth)	590470806020TBUZ
6020TB10		
6020TB10S		
6020TB5S		
6020TB9		
6020TB9S		
6020TB7		
6030TB2	Selenite F Broth	590470806030TBV8
6030TB10		
6030TB5S		
6030TB5		
6030TB3		
6030TB9		
6030TB8		

6030TB9S		
6035TB5	Sabouraud Dextrose Broth + Chloramphenicol + Gentamycin	590470806035TBVZ
6070TB5	Kligler Iron Agar	590470806070TBW4
6070TB7		
6080TB3	Tryptic Soy Broth (TSB)	590470806080TBWB
6080TB2		
6080TB5		
6080TB10		
6080TB5S		
6080TB9		
6080TB10(S)		
6080TB9S	Todd-Hewitt Broth + Colistin + Nalidixic Acid	590470806088TBXK
6088TB10(S)		
6088TB5		
6088TB5S	Todd-Hewitt Broth + Gentamycin + Nalidixic Acid	590470806089TBXQ
6089TB5		
6089TB2		
6089TB1		
6089TB10S		
6089TB5S		
6089TB9	Todd-Hewitt Broth	590470806090TBWJ
6090TB3		
6090TB5		
6090TB9	Enterococcosel Agar	590470806091TBWP
6091TB7		
6091TB3	Brucella Broth	590470806095TBXB
6095TB5		
6095TB3	Tryptic Soy Broth + 20% Glycerol (TSB +20% Glycerol)	590470806099TBXX
6099TB0,9-1,2		
6099TB1,5		
6099TB5		
6099TB2	Schaedler Broth	590470806100TBUW
6100TB10		
6100TB10S		
6100TB9		
6100TB8S		
6100TB5	Schaedler Broth + Vit.K3 + 0,2% Agar	590470806101TBV3
6101TB10		
6101TB10S		

6102TB10	Schaedler Broth + Vit.K3 + 0,02% Agar	590470806102TBV8
6102TB9S		
6102TB10S		
6111TB7	Christensen Agar	590470806111TBVA
6111TB5		
6112TB7	Christensen Agar for dermatophytes	590470806112TBVF
6122TB5	6,5% Sodium Chloride Broth	590470806122TBVZ
6122TB5S		
6124TB3	Kligler Iron Agar	590470806124TBVY
6124TB7S		
6125TB3	Simmons Citrate Agar	590470806125TBW5
6126TB3	Phenylalanine Agar	590470806126TBWA
6127TB3	Maloniate Broth	590470806127TBWF
6127TB5		
6127TB2		
6127TB5S		
6127TB1		
6127TB10		
6128TB3	Bromocresol Purple Broth + 10% Lactose	590470806128TBWL
6128TB3S		
6129TB3	Falkow Decarboxylase Broth + Lysine	590470806129TBWR
6130TB3	Falkow Decarboxylase Broth + Arginine	590470806130TBVK
6130TB5		
6131TB3	Falkow Decarboxylase Broth + Ornithine	590470806131TBVQ
6132TB3	Falkow Decarboxylase Broth control	590470806132TBVV
6133TB3	Christensen Broth	590470806133TBW2
6136TB3S	1% Peptone Water + Tryptophane	590470806136TBWH
6136TB3,5		
6136TB5		
6136TB5S		
6136TB8		
6137TB3	Indole - Urease Medium	590470806137TBWN
6141TB3	PP Red Agar	590470806141TBVX
6141TB5		
6147TB3	Clark Broth	590470806147TBWV
6149TB5	0,9% NaCl Solution	590470806149TBX7
6149TB2		
6149TB3		
6149TB5S		
6149TB9		
6149TB4,5		
6149TB3S		

6149ATB2	3% NaCl Solution	
6149ATB5		
6152TB2	2% Sodium Deoxycholate	590470806152TBWB
6152TB0,5		
6153TB2	Phenylboronic Acid	590470806153TBWG
6153TB2S		
6155TB2	EDTA	590470806155TBWS
6155TB2S		
6209TB5	1% Glucose Broth	590470806209TBWN
6209TB3		
6209TB5S		
6241TB3	PP Agar Modified	590470806241TBWA
6241TB3S		
6249TB2	0,85% NaCl Solution	590470806249TBXJ
6249TB2,5		
6249TB2S		
6249TB3S		
6249TB5		
6249TB9		
6301TB7	Sabouraud Dextrose Agar + Chloramphenicol + Gentamycin	590470806301TBVR
6303TB7	Sabouraud Dextrose Agar + Chloramphenicol	590470806303TBW3
6304TB7	Sabouraud Dextrose Agar + Chloramphenicol + Actidione	590470806304TBW8
6304TB7S		
TN2102	Dermatophytes Agar Modified	59047080TN2102ES
TN2125	Yeast Extract Cysteine Blood Agar (HCB)acc.to Beerens	59047080TN2125F6
TN2117	Chocolate Agar	59047080TN2117F7

Imię i nazwisko / Name :

Stanowisko / Position :

Podpis / Signature : (-)