



RESOLUÇÃO - RE Nº 1.901, DE 16 DE MAIO DE 2014

O Diretor-Presidente Substituto da Agência Nacional de Vigilância Sanitária no uso das atribuições que lhe confere o Decreto de recondução de 09 de maio de 2014, da Presidenta da República, publicada no DOU de 12 de maio de 2014, designado substituto pela Portaria MS/GM nº 912, de 12 de maio de 2014, e o inciso X do art. 13 do Regulamento da ANVISA, aprovado pelo Decreto nº 3.029, de 16 de abril de 1999, tendo em vista o disposto no inciso VIII do art. 16 e no inciso I, § 1º do art. 55 do Regimento Interno da ANVISA, aprovado nos termos do Anexo I da Portaria n.º 354, de 11 de agosto de 2006, republicada no DOU de 21 de agosto de 2006 e considerando o art. 12 e o art. 25 da Lei n.º 6.360, de 23 de setembro de 1976, bem como o inciso IX, do art. 7º da Lei n.º 9.782, de 26 de janeiro de 1999, resolve:

Art. 1º Conceder o Registro, Cadastro e o Cadastramento dos processos dos Produtos para a Saúde, na conformidade da relação anexa.

Art. 2º Esta Resolução entra em vigor na data de sua publicação

JAIME CESAR DE MOURA OLIVEIRA

ANEXO

NOME DA EMPRESA AUTORIZAÇÃO  
NOME TÉCNICO NUMERO DO PROCESSO  
NOME COMERCIAL  
LOCAL DE FABRICAÇÃO  
MODELO(S) DO PRODUTO  
CLASSE REGISTRO  
PETIÇÃO(ÕES)  
ALERE S/A 1.00717-7  
FILARIOSE (ELEFANTÍASE) 25351.061517/2014-60  
BinaxNOW Filariose  
FABRICANTE : ALERE SCARBOROUGH, INC. - ESTADOS UNIDOS  
kit para 25 testes  
CLASSE : II 10071770759  
8002 - Registro de Produtos para Diagnóstico de uso in vitro, Importado  
ALIVE HEART MATERIAL MÉDICO LTDA 8.04154-4  
Torneiras 25351.208557/2014-53  
TORNEIRA VALVULADA  
FABRICANTE : ELCAM MEDICAL ACAL - ISRAEL  
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CLASSE : II 80415440014  
80007 - Cadastro de Famílias de Material de Uso Médico IMPORTADO  
ALLIED TITANIUM LTDA ME 8.02543-5  
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04.04.0109.2107; 04.04.0109.2

Asp. 44; Tubo C Asp.45; Tubo C com extensão Asp. 45; Tubo S 202 Oxigenação; Tubo S 202 com extensão Oxigenação; Tubo S 203 Oxigenação; Tubo S 203 com extensão Oxigenação; Tubo S 204 Oxigenação; Tubo S 204 com extensão Oxigenação; Tubo S Oxi.g.1; Tubo S com extensão Oxi.g. 1; Tubo S Oxi.g.2; Tubo S com extensão Oxi.g. 2; Tubo S Oxi.g.3; Tubo S com extensão Oxi.g. 3; Tubo S Oxi.g.4; Tubo S com extensão Oxi.g. 4; Tubo S Oxi.g.5; Tubo S com extensão Oxi.g. 5; Tubo S Oxi.g.6; Tubo S com extensão Oxi.g. 6; Tubo S Oxi.g.7; Tubo S com extensão Oxi.g. 7; Tubo S Oxi.g.8; Tubo S com extensão Oxi.g. 8; Tubo S Oxi.g.9; Tubo S com extensão Oxi.g. 9; Tubo S Oxi.g.10; Tubo S com extensão Oxi.g. 10; Tubo S Oxi.g.11; Tubo S com extensão Oxi.g. 11; Tubo S Oxi.g.12; Tubo S com extensão Oxi.g. 12; Tubo S Oxi.g.13; Tubo S com extensão Oxi.g. 13; Tubo S Oxi.g.14; Tubo S com extensão Oxi.g.14; Tubo S Oxi.g.15; Tubo S com extensão Oxi.g. 15; Tubo S Oxi.g.16; Tubo S com extensão Oxi.g. 16; Tubo S Oxi.g.17; Tubo S com extensão Oxi.g. 17; Tubo S Oxi.g.18; Tubo S com extensão Oxi.g. 18; Tubo S Oxi.g.19; Tubo S com extensão Oxi.g. 19; Tubo S Oxi.g.20; Tubo S com extensão Oxi.g. 20; Tubo C 202 Oxigenação; Tubo C 202 com extensão Oxigenação; Tubo C 203 Oxigenação; Tubo C 203 com extensão Oxigenação; Tubo C 204 Oxigenação; Tubo C 204 com extensão Oxigenação; Tubo C Oxigenação; Tubo C com extensão Oxigenação; Tubo C Oxi.g.1; Tubo C com extensão Oxi.g. 1; Tubo C Oxi.g.2; Tubo C com extensão Oxi.g. 2; Tubo C Oxi.g.3; Tubo C com extensão Oxi.g. 3; Tubo C Oxi.g.4; Tubo C com extensão Oxi.g. 4; Tubo C Oxi.g.5; Tubo C com extensão Oxi.g. 5; Tubo C Oxi.g.6; Tubo C com extensão Oxi.g. 6; Tubo C Oxi.g.7; Tubo C com extensão Oxi.g. 7; Tubo C Oxi.g.8; Tubo C com extensão Oxi.g. 8; Tubo C Oxi.g.9; Tubo C com extensão Oxi.g. 9; Tubo C Oxi.g.10; Tubo C com extensão Oxi.g. 10.

CLASSE : II 80106750012

80009 - Cadastro de Famílias de Material de Uso Médico NACIONAL

CONCISE COM APAR EQUIP ELETRO-ELETRONICOS LTDA 8.00063-4

Bomba de Infusão 25351.386062/2013-37

BOMBA DE INFUSAO JMS

FABRICANTE : MED-TECH INC. - JAPÃO

DISTRIBUIDOR : JMS CO., LTD - JAPÃO

DISTRIBUIDOR : JMS NORTH AMERICA CORPORATION - ESTADOS UNIDOS

OT-701

CLASSE : III 80006340004

8049 - Registro de Equipamento IMPORTADO, de Médio e Pequeno Porte

DENTSCLER INDÚSTRIA DE APARELHOS ODONTOLÓGICOS LTDA 1.03286-9

Equipos Odontologicos e Acessorios 25351.384531/2013-07

EQUIPAMENTO ODONTOLÓGICO E ACESSORIOS

FABRICANTE : DENTSCLER INDÚSTRIA DE APARELHOS ODONTOLÓGICOS LTDA - BRASIL

Unidade Dental Primax Equipo Primax FLX

CLASSE : II 10328690031

8054 - Registro de Equipamento NACIONAL, de Médio e Pequeno Porte

Diagno Comercio e Manipulação de Produtos Quimicos LTDA 8.00196-4

SOLUÇÃO DE LISE PARA HEMATOLOGIA 25351.113137/2014-92

Dialyse-AL

FABRICANTE : Diagno Comercio e Manipulação de Produtos Quimicos LTDA - BRASIL

1 L

450 ml

500 ml

CLASSE : I 80019640063

8434 - Cadastro de Produtos para Diagnóstico de uso in vitro, Nacional

DORJA INDÚSTRIA E COMERCIO DE EQUIPAMENTOS MÉDICOS LTDA 1.03321-7

Aparelho Para Nebulizacao de Medicamentos 25351.019725/2013-22

INALADOR / NEBULIZADOR MEDICATE

FABRICANTE : DORJA INDÚSTRIA E COMERCIO DE EQUIPAMENTOS MÉDICOS LTDA - BRASIL

DISTRIBUIDOR : DORJA INDÚSTRIA E COMERCIO DE EQUIPAMENTOS MÉDICOS LTDA - BRASIL

MD4000

CLASSE : II 10332179005

8057 - Cadastramento (isenção) de Equipamento para Saúde NACIONAL

EDWARDS LIFESCIENCES COMÉRCIO DE PRODUTOS MÉDICO-CIRÚRGICOS LTDA 8.02190-5

Cateteres 25351.465356/2012-92

dispositivo de oclusão intra-aórtico intraclude

FABRICANTE : EDWARDS LIFESCIENCES LLC. - ESTADOS UNIDOS

DISTRIBUIDOR : EDWARDS LIFESCIENCES LLC. - ESTADOS UNIDOS

ICF100.

CLASSE : IV 80219050151

8027 - Registro de Famílias de Material de Uso Médico IMPORTADO

**EIC BRASIL EXPORTADORA DE PRODUTOS INDUSTRIALIZADOS LTDA 8.05182-7**

Extrator de Calculos 25351.198113/2014-79

**Sonda Extratora de Cálculo em Nitinol Flex ALLWIN**

FABRICANTE : SURGIMEDIK HEALTHCARE - ÍNDIA

DISTRIBUIDOR : ALLWIN MEDICAL DEVICES - ESTADOS UNIDOS

DISTRIBUIDOR : SURGIMEDIK HEALTHCARE - ÍNDIA

TRAPPER: TNB 4W/1.8F-90-PA; TNB 4W/1.8F-120-PA; TNB 4W/3F-90-PA; TNB 4W/3F-120-PA; TNB 4W/4F-90-PA; TNB 4W/4F-120-PA; TNB 4W/2.4F-90-PA; TNB 4W/2.4F-120-PA; FLATWIRE: NITI 4W/2.4F-90-F-PA; NITI 4W/2.4F-120-F-PA; NITI 4W/3F-90-F-PA; NITI 4W/3F-120-F-PA; NITI 4W/4F-90-F-PA; NITI 4W/4F-120-F-PA; HELICAL: NITI 4W/2.4F-90-H-PA; NITI 4W/2.4F-120-H-PA; NITI 4W/3F-90-H-PA; NITI 4W/3F-120-H-PA; NITI 4W/4F-90-H-PA; NITI 4W/4F-120-H-PA;

CLASSE : II 80518270016

80007 - **Cadastro de Famílias de Material de Uso Médico IMPORTADO**

Extrator de Calculos 25351.198147/2014-31

**Sonda Extratora de Cálculo em Nitinol ALLWIN**

FABRICANTE : SURGIMEDIK HEALTHCARE - ÍNDIA

DISTRIBUIDOR : ALLWIN MEDICAL DEVICES - ESTADOS UNIDOS

DISTRIBUIDOR : SURGIMEDIK HEALTHCARE - ÍNDIA

TRAPPER: TNB 4W/3F-90; TNB 4W/3F-120; TNB 4W/4F-90; TNB 4W/4F-120; FLATWIRE: NITI 4W/3F-90-F; NITI 4W/3F-120-F; NITI 4W/4F-90-F; NITI 4W/4F-120-F; HELICAL: 4W/3F-90-H; NITI 4W/3F-120-H; NITI 4W/4F-90-H; NITI 4W/4F-120-H;

CLASSE : II 80518270017

80007 - **Cadastro de Famílias de Material de Uso Médico IMPORTADO**

ENDOCIRÚRGICA COMÉRCIO DE PRODUTOS MÉDICOS LTDA 1.03892-1

Brocas Odontologicas 25351.196892/2014-51

BROCAS TUNGSTÊNIO CARBIDE ACURATA

FABRICANTE : acurata G + K MAHNHARDT dENTAL E.k. - ALEMANHA

500 204 001 SQ 006, 500 204 001 SQ 008, 500 204 001 SQ 010, 500 204 001 SQ 012, 500 204 001 SQ 014, 500 204 001 SQ 016, 500 204 001 SQ 018, 500 204 001 SQ 021, 500 204 001 SQ 023, 500 204 001 SQ 025, 500 204 001 SQ 027, 500 204 001 SQ 029, 500 205 001 SQ

010, 500 205 001 SQ 012, 500 205 001 SQ 014, 500 314 249 080 012, 500 205 001 SQ 016, 500 205 001 SQ 018, 500 205 001 SQ 021, 500 205 001 SQ 023, 500 315 001 SQ 010, 500 315 001 SQ 012, 500 315 001 SQ 014, 500 315 001 SQ 016, 500 204 001 175

010, 500 204 001 175 012, 500 204 001 175 014, 500 204 001 175 016, 500 204 001 175 018, 500 204 001 175 021, 500 204 001 175 023, 500 204 001 175 027, 500 204 001 175 029, 500 205 001 175

010, 500 205 001 175 014, 500 205 001 175 018, 500 205 001 175 023, 500 315 001 175 010, 500 315 001 175 012, 500 315 001 175 014, 500 315 001 175 016, 500 315 001 175 018, 500 315 001 175 021, 500 314 168 141

012, 500 314 168 141 012, 500 314 139 141 012, 500 314 194 141 012, 500 314 237 015 010, 500 314 237 015 012, 500 314 238 015 012, 500 314 139 015 012, 500 314 138 293 012, 500 314 194 007

015, 500 314 137 SCC 010, 500 314 139 SCC 012, 500 314 140 SCC 012, 500 314 141 080 012, 500 314 141 080 014, 500 314 198 080 016, 500 314 277 080 023, 500 314 289 080 012, 500 314 001 071

018, 500 314 001 071 023, 500 314 159 071 010, 500 314 164 071 014, 500 314 166 071 014, 500 314 699 071 008, 500 314 158 072

012, 500 314 199 072 016, 500 314 238 072 014, 500 314 243 072 009, 500 314 243 072 010, 500 314 243 072 012, 500 314 249 072

012, 500 314 257 072 014, 500 314 257 072 018, 500 314 257 072 023, 500 314 274 072 014, 500 314 274 072 018, 500 314 277 072 012, 500 314 277 072 018, 500 314 277 072 023, 500 314 288 072

010, 500 314 288 072 012, 500 314 289 072 012, 500 314 290 072 014, 314 544 072 023, 500 314 215 072 014, 500 314 159 042 010,

500 314 164 042 014, 500 314 166 042 014, 500 314 249 042 012, 500 314 274 042 014, 500 314 274 042 018, 500 314 277 042 014, 500 314 277 042 018, 500 314 277 042 023, 500 314 199 032 016,

500 314 274 032 014, 500 314 274 032 018, 500 314 289 032 012, 500 314 249 032 012, 500 314 277 032 012, 500 314 277 032 014, 500 314 277 032 016, 500 314 243 FQ 009,

500 314 249 FQ 012, 500 314 166 FQ 014, 500 314 277 FQ 023, 500 204 001 291 005, 500 204 001 291 006, 500 204 001 291 008, 500 204 001 291 010, 500 204 001 291 012, 500 204 001 291 014, 500 204 001 291 016, 500 204 001 291 018, 500 204 001 291 021, 500 204 001 291 023, 500 204 010 001 010, 500 314 010 001 012, 500 204 010 001 014, 500 204 010 001 016, 500 204 010 001 018, 500 204 194 006 016, 500 204 218 006 018, 500 204 297 HOS 016, 500 204 194 HOS 016, 500 204 198 HOS 016, 500 314 107 006 008, 500 314 107 006 010, 500 314 107 006 012, 500 314 107 006 014, 500 314 107 006 016, 500 314 137 006 010, 500 314 137 006 012, 500 314 137 006 014, 500 204 194 006 010, 500 204 194 006 012, 500 314 110 006 010, 500 314 110 006 012, 500 314 110 006 014, 500 314 168 006 010, 500 314 168 006 012, 500 314 168 006 016, 500 314 237 006 008, 500 314 237 006 010, 500 314 237 006 012, 500 314 219 295 016, 500 316 219 295 016, 500 316 254 297 012, 500 317 254 297 012, 500 205 254 297 012, 500 104 254 297 012, 500 205 254 297 016, 500 104 254 297 016, 500 316 408S 297 016, 500 205 408S 297 016, 500 205 409S 297 021, 500 104 408S 297 016, 500 104 409S 297 021, 500 106 408S 297 016, 500 106 408S 297 016, 500 205 001 251 027, 500 205 001 251 031, 500 205 001 251 035, 500 205 001 251 040, 500 104 001 251 027, 500 104 001 251 031, 500 104 001 251 035, 500 104 001 251 040, 506 205 001 291 010, 506 205 001 291 014, 506 205 001 291 018, 506 205 001 291 023, 506 205 001 291 027, 506 205 001 291 031, 506 205 001 291 035, 506 205 001 291 040, 506 205 001 291 050, 506 205 001 298 023, 506 205 001 298 027, 506 205 001 298 031, 506 205 001 298 035, 506 205 001 298 040, 506 205 408 298 016, 506 316 408 298 016, 506 205 409 298 021, 506 205 408 297 016, 506 316 408 297 016, 506 205 407 297 018, 506 205 409 297 021, 506 205 408 295 016, 506 316 408 295 016, 506 316 199 295 016, 500 314 197 295 016

CLASSE : I 10389210002

80007 - Cadastro de Famílias de Material de Uso Médico IMPORTADO

ENTERPRISES IMP E COM DE PRODS MED E HOSP LTDA 1.03609-3

Instrumentos cirúrgicos 25351.075230/2014-75

INSTRUMENTAL CIRÚRGICO ARTICULADO NÃO CORTANTE JEIL

FABRICANTE : JEIL MEDICAL CORPORATION - CORÉIA DO SUL

DISTRIBUIDOR : JEIL MEDICAL CORPORATION - CORÉIA DO SUL

3-Prong Mini Plate Bender - 111-023; Micro Mini Plate Bender - 111-024; Micro/Mid Holding Forcep - 111-031; Mini/Max Holding Forcep - 111-032; Maxi Plate Bender - 111-033; 3D Mesh R-Former - 111-040; Separator For Mandibular Bone - 111-043; Mandible Reduction Forceps - MRF-SYM.

CLASSE : I 10360930023

80007 - Cadastro de Famílias de Material de Uso Médico IMPORTADO

Instrumentos cirúrgicos 25351.075240/2014-97

INSTRUMENTAL CIRÚRGICO NÃO ARTICULADO CORTANTE JEIL

FABRICANTE : JEIL MEDICAL CORPORATION - CORÉIA DO SUL

DISTRIBUIDOR : JEIL MEDICAL CORPORATION - CORÉIA DO SUL

Micro Drill Bit For Angle (8 mm Stop) - 112-MC-201; Micro Drill Bit For Angle (12 mm Stop) - 112-MC-202; Short Micro Drill Bit (12 mm Stop) - 112-MC-302; Drill Bit (Stop) - 112-MC-Stop; Short Mid Drill Bit For Angle (10 mm Stop) - 112-MD-201; Short Mid Drill Bit For Angle (14 mm Stop) - 112-MD-301; Long Mid Drill Bit (14 mm Stop) - 112-MD-302; Drill Bit (Stop) - 112-MD-Stop; Mini Drill Bit For Angle (8 mm Stop) - 112-MN-201; Mini Drill Bit For Angle (12 mm Stop) - 112-MN-202; Short Mini Drill Bit (12 mm Stop) - 112-MN-301; Short Mini Drill Bit (22 mm Stop) - 112-MN-302; Long Mini Drill Bit (22 mm Stop) - 112-MN-303; Long Mini Drill Bit (6 mm Stop) - 112-MN-306; Drill Bit (Stop) - 112-MN-Stop; Short Mini Drill Bit (12 mm Stop) - 112-MU-301; Short Mini Drill Bit (22 mm Stop) - 112-MU-302; Short Maxi Drill Bit - 112-MX-201; Maxi Drill Bit - 112-MX-202; Short Maxi Drill Bit (24 mm Stop) - 112-MX-301; Long maxi Drill Bit (47 mm Stop) - 112-MX-302; Long Micro Drill Bit (12 mm Stop) - 122-MC-301.

CLASSE : I 10360930024

80007 - Cadastro de Famílias de Material de Uso Médico IMPORTADO

EURODENTAL COMERCIAL IMPORTADORA LTDA EPP 8.07864-6

Brocas Odontologicas 25351.192515/2014-61

BROCAS EM CARBETO DE TUNGSTÊNIO NTI-KAHLA

FABRICANTE : NTI-Kahla GmbH - Rotary Dental Instruments - ALEMANHA

001 - HP: Diâmetros: 014;023;014;023;023;029;040;045mm. 002 - HP: Diâmetros: 023;023;008;016;023;023;023;040;060mm. 003 - HP: Diâmetros: 023;023;023;023mm. 004 - HP: Diâmetros: 045;008;009;010;023;023mm. 005 - HP: Diâmetros: 023;023;023mm. 006 - HP: Diâmetros: 023;060;014;023;014;023;060;012;040mm. 007 - HP: Diâmetros: 060;023;060;045;060;023;023;016;023mm. 008 - HP: Diâmetros: 023;060;060;023;023mm. 009 - HP: Diâmetros: 023;010;012;023;040;060;023;014mm. 010 - HP: Diâmetros: 010;012;014;016;018;023;025;027;031mm. 011 - HP: Diâmetros: 035;040;050;060;080;060;014;023;060mm. 012 - HP: Diâmetros: 023;023;029;060;060;012;023;040;060mm. 013 - HP: Diâmetros: 031;040;045;060;023;016;023;008;009mm. 014 - HP: Diâmetros: 010;016;023;023;040;060;060;023;060mm. 015 - HP: Diâmetros: 023;023;023;060;040;060;023;014mm. 016 - HP: Diâmetros: 027;031;040;050;060;060;031;040;045mm. 017 - HP: Diâmetros: 060;009;010;040;060;060;060;060mm. 018 - HP: Diâmetros: 060;060;060;045;060;060;060mm. 019 - HP: Diâmetros: 060;045;060;060mm. 020 - HP: Diâmetros: 060;070;060mm. 021 - HP: Diâmetros: 070;060mm. 022 - HP: Diâmetros: 045;060;060mm. 023 - HP: Diâmetros: 040;045;023;060;060;070mm. 024 - HP: Diâmetros: 045;023mm. 025 - HP: Diâmetros: 045mm. 026 - HP: Diâmetros: 023;040;023;023;023;040;060;023;023mm. 027 - HP: Diâmetros: 008;009;010mm. 028 - HP: Diâmetros: 040;023;008;016;023;023;060mm. 028 - HP: Diâmetros: 040;023;016;023;023mm. 030 - HP: Diâmetros: 045;023;045;060mm. 031 - HP: Diâmetros: 023;023mm. 032 - HP: Diâmetros: 023mm. 033 - HP: Diâmetros: 060mm. H1 - HP: Diâmetros: 002;003;004;005;006;007;008;009;010;012;014;016;018;021;023;027mm. H2 - HP: Diâmetros: 008;010;012;014;016;018mm. H7 - HP: Diâmetros: 006;008mm. H21 - HP: Diâmetros: 008;009;010;012;014;016mm. H21L - HP: Diâmetros: 010;012mm. H23 - HP: Diâmetros: 008;009mm. H23L - HP: Diâmetros: 012mm. H23R - HP: Diâmetros: 010mm. H31 - HP: Diâmetros: 008;010;012;014;016mm. H33 - HP: Diâmetros: 008;009;010;021mm. H33L - HP: Diâmetros: 012mm. H30X - HP: Diâmetros: 010