



Ministerio de Salud y Desarrollo Social
Secretaría de Gobierno de Salud
A.N.M.A.T.

DECLARACIÓN DE CONFORMIDAD DE REVÁLIDA – PM CLASE I- II

Número de revisión: 01

Fecha de Vigencia de la Declaración revisión 00-Disposición Autorizante o Reválida: 27/03/2019

Número de PM:

108-117

Nombre Descriptivo del producto:

INSTRUMENTAL MEDICO QUIRÚRGICO GENERAL

Código de identificación y nombre técnico UMDNS:

15-621 INSTRUMENTAL PARA MICROCIRUGIA

Clase de Riesgo:

Clase I

Marca de (los) producto(s) médico(s):

TRIMED

Modelos (en caso de clase II y equipos):

Adenotomos

23-860-01; 23-861-01; 23-860-02; 23-861-02; 23-860-03; 23-861-03; 23-860-04; 23-861-04; 23-860-05; 23-860-06; 23-861-06; 23-866-01; 23-866-02; 23-866-03; 23-866-04; 23-870-01; 23-870-02; 23-870-03; 23-870-04; 23-880-01; 23-880-02; 23-880-03; 23-882-01; 23-882-02; 23-882-03.

Anoscopios

18-741-15; 18-745-16; 18-745-23; 18-761-01; 18-761-02; 18-761-03; 18-761-04; 18-763-19; 18-765-05; 18-765-18; 18-765-14; 18-765-22; 18-767-21; 18-767-27.

Pinza para tubos

07-720-14; 07-724-16; 07-730-15; 07-730-18; 07-730-20; 07-734-15; 07-734-18; 07-734-20; 29-754-12; 29-754-16; 29-754-20; 29-754-24; 29-758-12; 29-762-13; 29-762-17; 29-762-20; 29-762-

25; 29-762-30; 29-762-40; 29-762-50.

Cinceles

13-271-08; 13-271-10; 13-271-12; 13-271-14; 13-271-16; 13-275-02; 13-275-03; 13-275-04; 13-275-05; 13-275-06; 13-284-04; 13-284-06; 13-284-08; 13-284-10; 13-284-12; 13-284-14; 13-293-10; 13-293-15; 13-293-20; 13-293-25; 13-333-06; 13-333-13; 13-333-19; 13-333-25; 13-333-32; 23-624-03; 23-630-04; 23-630-05; 23-630-06; 23-630-07; 23-632-10; 23-632-12; 23-632-14; 23-632-16; 23-650-23; 23-652-01; 23-652-02; 23-652-03; 23-654-01; 23-654-02; 23-654-03; 23-656-01; 23-656-02; 23-656-03.

Clamps para arteria

14-508-18; 14-508-20; 14-508-23; 14-508-25; 14-671-15; 14-673-16; 14-675-16; 14-401-23; 14-405-21; 14-447-16; 14-449-19; 14-449-20; 14-621-17; 14-623-17; 14-625-17; 07-110-03; 07-110-05; 07-110-06; 07-111-03; 07-111-05; 07-111-06; 07-114-04; 07-114-05; 07-114-06; 07-114-07; 07-114-09; 07-115-04; 07-115-05; 07-115-06; 07-115-07; 07-115-09; 07-120-8; 07-120-10; 07-120-12; 07-221-08; 07-121-10; 07-121-12; 07-124-10; 07-124-14; 07-124-20; 07-125-10; 07-125-14; 07-125-20; 07-130-30; 07-130-35; 07-130-40; 07-130-50; 07-140-30; 07-140-30; 07-140-35; 07-140-40; 07-140-50; 07-131-30; 07-131-35; 07-131-40; 07-131-50; 07-141-30; 07-141-35; 07-141-50; 07-133-30; 07-133-35; 07-133-35; 07-133-40; 07-133-50; 07-143-30; 07-143-35; 07-143-40; 07-143-50; 14-331-07; 14-331-09; 14-331-10; 14-333-05; 14-335-07; 14-337-09; 14-337-11; 14-339-01; 14-339-02; 14-340-07; 14-340-08; 14-340-10; 14-340-12; 14-341-07; 14-341-08; 14-341-10; 14-341-11; 14-346-06; 14-346-07; 14-346-09; 14-346-11; 14-347-05; 14-347-06; 14-347-08; 14-347-10; 14-349-23.

Pinza para hueso

13-178-09; 13-178-13; 13-178-18; 13-178-20; 13-178-22; 13-179-15; 13-179-18; 13-179-20; 13-179-22.

Pinza Clamp para bronquios

07-431-15; 07-431-19; 07-433-15; 07-433-19; 07-437-22; 07-439-23; 07-451-18; 07-455-19; 07-457-23; 07-459-24; 14-303-22; 14-307-24; 14-309-24; 14-301-22; 14-303-22; 14-305-22; 14-307-24; 14-309-24. -

Disectores

15-250-25; 15-252-18; 15-252-24; 15-256-19; 15-256-24; 15-261-21; 15-263-21; 15-265-21; 15-267-22; 15-280-01; 15-280-02; 15-280-03; 15-280-04; 15-280-05; 15-283-24; 15-287-01; 15-287-02; 15-287-03; 15-300-19; 15-301-19; 15-303-19; 15-307-20; 15-307-20; 15-315-21; 15-330-23; 15-331-24; 15-333-20; 15-337-21; 15-350-08; 15-350-11; 15-350-14; 15-350-17; 15-350-20; 15-353-18; 15-355-18; 15-357-18; 15-359-18; 15-363-18; 15-365-18; 15-367-18; 15-369-18; 26-294-13; 26-698-13; 25-177-06; 25-177-10; 25-181-23; 25-183-23; 22-190-01; 22-190-02; 22-190-03; 22-190-04; 25-231-23.

Pinzas hemostáticas

07-170-14; 07-170-16; 07-176-13; 07-176-14; 07-176-15; 07-176-18; 07-176-20; 07-177-13; 07-177-14; 07-177-15; 07-177-18; 07-177-20; 07-181-01; 07-181-02; 07-186-10; 07-187-10; 07-189-12; 07-190-12; 07-190-14; 07-191-12; 07-191-14; 07-192-12; 07-192-14; 07-193-12; 07-193-14; 07-200-18; 07-201-18; 07-202-18; 07-203-18; 07-200-21; 07-201-21; 07-202-21; 07-203-21; 07-210-10; 07-210-12; 07-211-10; 07-211-12; 07-212-10; 07-213-10; 07-213-10; 07-213-12; 07-220-14; 07-221-14; 07-222-15; 07-223-15; 07-224-15; 07-225-15; 07-230-14; 07-231-14; 07-234-16; 07-235-16; 07-239-13; 07-240-14; 07-241-14; 07-242-14; 07-243-14; 07-250-16; 07-251-16; 07-252-15; 07-254-15; 07-255-12; 07-257-14; 07-259-14; 07-260-18; 07-261-18; 07-262-18; 07-263-18; 07-266-16; 07-266-20; 07-267-16; 07-267-20; 07-270-13; 07-272-08; 07-274-08; 07-277-13; 07-277-15; 07-278-16; 07-279-16; 07-280-13; 07-280-14; 07-280-16; 07-281-13; 07-281-14; 07-281-16; 07-286-13; 07-286-14; 07-286-16; 07-286-13; 07-286-14; 07-286-16; 07-287-14; 07-286-16; 07-287-13; 07-287-14; 07-287-16; 07-290-14; 07-290-16; 07-290-18; 07-291-14; 07-291-18; 07-296-14; 07-296-16; 07-296-18; 07-297-14; 07-297-16; 07-297-18; 07-300-20; 07-301-20; 07-302-20; 07-303-20; 07-300-26; 07-301-26; 07-302-26; 07-303-26; 07-310-14; 07-310-16; 07-310-

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Espejos laríngeos

25-650-08; 25-650-10; 25-650-12; 25-650-14; 25-650-16; 25-650-18; 25-650-20; 25-650-22; 25-650-24; 25-650-26; 25-650-28; 25-650-30; 25-654-08; 25-654-10; 25-654-12; 25-654-14; 25-654-16; 25-654-18; 25-654-20; 25-654-22; 25-654-24; 25-654-26; 25-654-28; 25-654-30; 25-661-12; 25-661-14; 25-661-16; 25-661-18.

Alicates

29-120-14; 29-124-14; 29-124-16; 29-128-11; 29-128-13; 29-132-13; 29-136-12; 29-140-11; 29-140-13; 29-140-15; 29-144-11; 29-144-13. -

Cuchillos

04-100-01; 04-100-04-100-02; 04-100-03; 04-100-04; 04-100-05; 04-100-06; 04-100-07; 04-100-08; 04-100-09; 04-100-10; 04-101-06; 04-101-07; 04-101-08; 04-101-09; 04-101-10; 04-102-01; 04-102-02; 04-102-03; 04-102-04; 04-102-05; 04-102-06; 04-103-01; 04-103-02; 04-103-03; 04-103-04; 04-103-05; 04-103-06; 04-103-07; 04-103-04; 04-103-05; 04-103-06; 04-103-07; 04-103-08; 04-110-08; 04-120-10;

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Leznas

24-641-18; 24-641-28; 24-645-13; 24-649-23; 24-671-15; 24-671-18; 33-180-08; 33-180-10; 33-180-12.

Diapasones

22-480-01; 22-480-02; 22-484-01; 22-484-02; 22-484-03; 22-488-01; 22-488-02; 22-488-03; 22-488-04; 22-488-05; 22-492-01; 22-492-02; 22-492-03; 22-492-04; 22-492-05; 22-492-06; 22-496-01; 22-496-02; 22-496-03; 22-496-04; 22-496-05; 22-496-06; 22-520-00; 22-524-00; 22-528-00; 22-530-00; 22-534-00; 22-538-00; 22-542-00.

INSTRUMENTOS MICROQUIRÚRGICOS

11-100-10; 11-101-10; 11-102-10; 11-103-10; 11-105-11; 11-105-13; 11-105-14; 11-106-14; 11-107-14; 11-109-01; 11-109-02; 11-110-15; 11-111-15; 11-112-15; 11-113-15; 11-121-14; 11-123-14; 11-125-14; 11-500-18; 11-504-18; 11-508-13; 11-508-15; 11-510-16; 11-510-18; 11-510-20;

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Perforadores de membrana amniótica

21-381-26.

Palillos para oído medio

22-164-06; 22-164-07; 22-164-08; 22-164-11; 22-164-12; 22-164-13; 22-164-14; 22-164-15; 22-164-16; 22-164-17; 22-164-21; 22-164-22; 22-164-23; 22-164-24; 22-164-25; 22-164-26; 22-164-27. -

Cortadores, alfiler y alambre

13-990-23; 13-992-37; 13-994-25; 13-996-40; 13-998-46; 13-998-54; 13-999-38; 13-999-45; 13-999-56; 13-222-23; 13-223-23; 13-224-01; 13-224-02; 13-224-03; 13-226-24; 13-228-32; 13-230-16; 13-232-16; 13-233-14; 13-234-15; 13-234-22; 13-235-17; 13-236-17; 13-237-16; 13-237-18; 13-237-22; 13-238-18.

Sondas

10-100-11; 10-100-13; 10-100-14; 10-100-16; 10-100-18; 10-100-20; 10-100-25; 10-100-30; 10-110-11; 10-110-13; 10-110-14; 10-110-16; 10-110-18; 10-110-20; 10-110-25; 10-110-30; 10-120-11; 10-120-13; 10-120-14; 10-120-16; 10-120-18; 10-120-20; 10-120-25; 10-120-30; 10-130-10; 10-140-13; 10-140-14; 10-140-16; 10-140-18; 10-140-20; 10-150-11; 10-150-13; 10-150-14; 10-150-16; 10-150-18; 10-150-20; 10-160-11; 10-160-13; 10-160-14; 10-160-16; 10-160-18; 10-170-14; 10-180-16; 10-190-16; 10-200-16; 10-201-16; 10-203-16; 10-205-16; 27-347-00; 27-347-01; 27-347-02; 27-347-03.

Clamps umbilicales

21-461-08; 21-465-09.

Aplicadores de clamps

11-926-12; 11-915-18; 15-181-15; 15-181-19; 11-183-15; 11-183-19; 15-186-16; 15-190-14; 15-200-23; 15-202-23; 15-210-01; 15-210-02; 15-212-01; 15-212-02; 15-216-01; 15-216-02; 15-218-01; 15-218-02.

Pinza suturas

11-924-12; 11-926-12; 11-928-13; 11-930-14.

Pinzas para compresas

07-671-09; 07-673-05; 07-673-09; 07-675-09; 07-681-11; 07-681-13; 07-683-11; 07-685-08; 07-685-11; 07-685-13; 07-685-15; 07-687-13; 07-687-15; 07-691-10; 07-691-13; 07-695-20; 07-697-10; 07-697-13; 07-699-14; 07-703-09; 07-705-11; 07-707-18; 07-713-16.

Dilatadores

14-732-00; 14-736-00; 19-230-01; 19-230-02; 19-230-03; 19-230-04; 19-230-05; 19-230-06; 19-230-07; 19-230-08; 19-230-09; 19-230-10; 19-230-11; 19-230-12; 19-230-13; 19-650-10; 19-650-11; 19-650-12; 19-650-13; 19-650-14; 19-650-15; 19-650-16; 19-650-17; 19-650-18; 19-650-19; 19-650-20; 19-650-21; 19-650-22; 19-650-23; 19-650-24; 19-650-25; 19-650-26; 19-650-27; 19-650-28; 19-650-29; 19-650-30; 19-656-08; 19-656-10; 19-656-12; 19-656-14; 19-656-16; 19-656-18; 19-656-20; 19-656-22; 19-656-24; 19-656-26; 19-656-28; 19-656-30; 19-656-32; 19-656-34; 19-656-36; 19-660-08; 19-660-09; 19-660-10; 19-660-11; 19-660-12; 19-660-13; 19-660-14; 19-660-15; 19-660-16; 19-660-17; 19-660-18; 19-660-18; 19-660-20; 19-660-21; 19-660-22; 19-660-

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Pinzas Gubias

13-841-01; 13-841-02; 13-843-12; 13-845-14; 13-846-01; 13-846-02; 13-847-14; 13-849-14; 13-850-17; 13-851-14; 13-853-17; 13-855-16; 13-856-16; 13-857-18; 13-858-02; 13-858-03; 13-859-18; 13-860-18; 13-861-18; 13-863-18; 13-864-16; 13-864-19; 13-865-16; 13-865-19; 13-866-15; 13-867-14; 13-869-14; 13-870-13; 13-871-20; 13-872-18; 13-873-18; 13-874-19; 13-875-15; 13-876-15; 13-877-15; 13-878-20; 13-789-20; 13-880-15; 13-880-02; 13-881-15; 13-881-02; 13-883-18; 13-885-18; 13-887-17; 13-889-20; 13-890-18; 13-891-18; 13-890-23; 13-891-23; 13-892-01; 13-892-02; 13-892-03; 13-892-04; 13-892-05; 13-892-06; 13-893-01; 13-893-02; 13-894-20; 13-897-01; 13-897-02; 13-898-02; 13-898-15; 13-899-02; 13-899-15; 13-900-02; 13-900-03; 13-900-04; 13-902-01; 13-902-02; 13-902-03; 13-903-22; 13-903-27; 13-904-23; 13-910-24; 13-912-24; 13-914-24; 13-916-22; 13-916-26; 13-917-22; 13-917-26; 13-921-24; 13-923-23; 13-926-23; 13-926-27; 13-927-23; 13-927-27; 13-930-30; 13-932-30; 13-936-03; 13-936-05; 13-936-08; 13-937-03; 13-937-08; 23-400-13; 23-401-13; 23-402-12; 23-403-12; 23-406-16; 23-420-03; 23-420-05; 23-426-17; 23-427-17; 23-430-17; 23-431-17; 23-441-03; 23-441-04; 23-441-05; 23-441-06; 23-447-20; 15-630-01; 15-630-02; 15-630-03; 15-630-04; 15-630-05; 15-630-06; 15-630-07; 15-630-08; 15-630-09; 15-631-01; 15-631-02; 15-631-03; 15-631-04; 15-631-05; 15-631-06; 15-631-07; 15-631-08; 15-631-09; 15-633-01; 15-633-02; 15-633-03; 15-633-04; 15-633-05; 15-633-06; 15-633-07; 15-633-08; 15-633-09; 15-640-25; 15-642-25; 15-644-27; 15-650-03; 15-650-05; 15-652-02; 15-652-03; 15-652-04; 15-656-02; 15-656-03; 15-656-04; 15-658-01; 15-658-02; 15-658-03; 15-710-02; 15-710-03; 15-710-04; 15-710-06; 15-712-02; 15-712-03; 15-712-04; 15-712-06; 15-714-02; 15-714-03; 15-714-04; 15-714-06; 15-750-01; 15-750-02; 15-750-03; 15-750-05; 15-752-01; 15-752-02; 15-752-03; 15-752-05; 15-754-01; 15-754-02; 15-754-03; 15-754-05; 15-760-01; 15-760-02; 15-760-03; 15-760-05; 15-762-01; 15-762-02; 15-762-03; 15-762-05; 15-764-01; 15-764-02; 15-764-03; 15-764-05; 15-770-01; 15-770-02; 15-770-03; 15-770-05; 15-772-

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Sierras, hueso, manual

13-100-12; 13-100-15; 13-100-18; 13-100-35; 13-110-23; 13-112-27; 13-114-31.

Cortadores de hueso

13-940-19; 13-941-16; 13-943-20; 13-946-14; 13-946-17; 13-946-19; 13-947-14; 13-947-17; 13-947-22; 13-948-15; 13-951-15; 13-951-17; 13-952-15; 13-953-15; 13-954-18; 13-955-18; 13-957-17; 13-960-15; 13-961-15; 13-962-15; 13-963-15; 13-965-12; 13-972-27; 13-973-24; 13-976-24; 13-978-23; 13-978-27; 13-970-23; 13-979-27.

Clamps para circuncisión

19-753-08; 19-755-08; 19-757-11.

Clamps intestinales

18-210-13; 18-211-13; 18-230-16; 18-231-16; 18-230-18; 18-231-18; 18-236-21; 18-236-23; 18-237-21; 18-237-23; 18-240-21; 18-240-23; 18-241-21; 18-241-23; 18-246-25; 18-247-25; 18-247-25; 18-250-22; 18-250-25; 18-250-28; 18-251-22; 18-251-25; 18-251-28; 18-260-25; 18-261-25; 18-264-25; 18-264-33; 18-265-25; 18-265-33; 18-280-24; 18-350-13; 18-351-13; 18-356-18; 18-356-20; 18-356-23; 18-370-13; 18-370-16; 18-370-18; 18-370-21; 18-370-23; 18-371-13; 18-371-16; 18-371-18; 18-371-21; 18-371-23; 18-380-25; 18-381-25; 18-386-22; 18-386-25; 18-386-28; 18-387-22; 18-387-25; 18-387-28; 18-400-33; 18-401-33; 18-410-24; 18-431-26; 18-431-28; 18-435-23; 18-437-24; 18-453-30; 18-501-15; 18-503-15; 18-511-21; 18-513-21; 18-517-29; 18-519-29; 18-523-35; 18-525-35; 18-600-30; 18-601-30; 18-606-36; 18-630-05; 18-630-07; 18-630-10; 18-637-26; 18-638-08; 18-638-23; 18-650-07; 18-650-10; 18-652-00; 18-654-15; 18-870-00; 18-880-19; 18-890-00; 18-896-30.

Jeringas para oído

22-944-02; 22-944-03; 22-944-04; 22-944-06; 22-944-07; 22-944-08; 22-944-09; 22-945-00; 22-945-04.

Elevadores

22-196-01; 22-196-02; 22-196-03; 22-196-04; 22-196-05; 22-196-06; 23-551-19; 23-553-19; 23-556-19; 23-557-19; 23-559-22; 23-563-23; 23-566-28; 23-570-23; 23-572-21; 23-579-22; 23-581-22; 23-583-21; 23-584-21; 23-585-16; 24-560-06; 24-560-07; 24-560-09; 24-560-11; 24-565-05; 24-565-07; 24-565-09; 24-580-01; 24-580-02; 24-586-21; 24-588-21; 15-250-25; 15-252-18; 15-252-24; 15-256-19; 15-256-24; 15-267-22; 15-550-05; 15-550-06; 15-565-02; 15-565-03; 15-565-04; 13-650-17; 13-651-17; 13-652-17; 13-653-17; 13-657-01; 13-657-02; 13-661-17; 13-663-16; 13-667-01; 13-667-02; 13-667-03; 13-667-04; 13-670-01; 13-670-02; 13-670-03; 13-673-23; 13-675-17; 13-677-17; 13-679-17; 13-681-17; 13-683-16; 13-685-16; 13-687-21; 13-689-19; 12-182-28; 13-683-17.

Pinzas

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Portaaguas

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Raspadores

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Retractores

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Agujas para biopsia

03-450-20; 03-450-25; 03-454-20; 03-454-25; 03-470-16; 03-476-18; 03-480-12; 03-480-14; 03-480-16; 03-484-01; 03-484-02; 03-484-03; 03-484-04; 03-484-05; 03-484-06; 03-484-07; 03-484-08; 03-488-14; 03-488-18; 03-500-14; 03-500-18; 03-506-01; 03-506-02; 03-506-03; 03-506-04; 03-506-05; 03-506-06; 03-514-20. -----

Pinza cortante Malleus

22-112-01; 22-112-06; 22-112-07.

Osteotomos para cirugía plástica

23-610-04; 23-610-07; 23-610-09; 23-610-12; 23-611-06; 23-613-06; 23-616-04; 23-616-07; 23-616-09; 23-616-12; 23-618-16; 23-620-16; 23-622-10; 23-622-12; 23-622-14; 23-626-03; 23-626-04; 23-626-07; 23-626-09; 23-626-12; 23-628-07; 23-628-08; 23-628-10; 23-628-12; 24-600-02; 24-600-04; 24-600-06; 24-606-23.

Otoscopios

01-302-01; 01-312-01; 01-340-01; 01-340-02; 01-340-03; 01-340-04; 01-340-05; 01-380-01; 01-380-02.

Pelvímetros

21-100-00; 21-104-00; 21-108-00; 21-110-00; 21-114-00.

Tijeras para disección

05-170-14; 05-170-15; 05-170-17; 05-170-23; 05-171-14; 05-171-15; 05-171-17; 05-171-23; 05-176-22; 05-176-30; 05-176-22; 05-177-30; 05-180-15; 05-180-17; 05-180-19; 05-180-21; 05-181-15; 05-181-17; 05-181-19; 05-181-21; 05-190-16; 05-191-16; 05-190-18; 05-191-18; 05-200-11; 05-201-11; 05-210-14; 05-212-14; 05-214-14; 05-211-14; 05-213-14; 05-215-14; 05-220-15; 05-221-15; 05-230-18; 05-230-20; 05-230-23; 05-230-25; 05-230-28; 05-230-30; 05-231-18; 05-231-20; 05-231-23; 05-231-25; 05-231-28; 05-231-30; 05-240-14; 05-241-14; 05-246-15; 05-247-15; 05-250-12; 05-250-19; 05-251-12; 05-251-19; 05-260-16; 05-261-16; 05-265-13; 05-267-19; 05-270-10; 05-271-10; 05-280-16; 05-281-16; 05-286-14; 05-287-14; 05-287-14; 05-288-14; 05-289-14; 05-290-18; 05-290-20; 05-290-23; 05-292-18; 05-292-20; 05-292-23; 05-292-25; 05-292-28; 05-292-30; 05-293-18; 05-293-20; 05-293-25; 05-293-28; 05-293-30; 05-294-18; 05-294-20; 05-294-23; 05-294-25; 05-294-28; 05-294-30; 05-295-18; 05-295-20; 05-295-23; 05-295-25; 05-295-28; 05-295-30; 05-432-11; 05-431-19; 05-432-14; 05-435-14; 05-437-17; 05-439-15; 05-440-15; 05-441-15; 05-442-01; 05-444-21; 05-446-18; 05-447-18; 05-450-23; 05-452-17; 05-453-17; 05-454-17; 05-456-17; 05-457-17; 05-458-17; 05-876-25; 05-876-45; 05-876-60; 05-876-90; 05-876-00; 05-877-25; 05-877-60; 05-877-90; 05-878-00; 05-320-15; 05-320-17; 05-321-15; 05-321-17;

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Polipotomos

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Sondas uterinas

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Espátulas

14-251-18; 14-251-21; 14-253-14; 14-253-23; 14-258-01; 14-258-02; 14-258-03; 14-258-04; 09-950-06; 09-950-09; 09-950-13; 09-950-16; 09-950-17; 09-950-25; 09-952-25; 09-956-30; 09-956-40; 09-956-50; 09-962-22; 09-968-30; 09-968-45; 09-968-50; 09-974-29; 14-281-30; 14-281-32; 26-590-13; 26-592-12; 26-592-13; 26-598-14; 26-600-09; 26-606-09.

Espéculos para oídos

22-401-01; 22-401-02; 22-401-03; 22-401-04; 22-405-00; 22-405-01; 22-405-02; 22-409-01; 22-409-02; 22-409-03; 22-409-04; 22-414-03; 22-414-04; 22-411-00; 22-411-01; 22-411-02; 22-411-03; 22-415-01; 22-415-02; 22-415-03; 22-415-04; 22-418-04; 22-419-01; 22-419-02; 22-419-03; 22-419-04; 22-420-00; 22-421-01; 22-421-02; 22-421-03; 22-421-04; 22-421-05; 22-421-06; 22-425-01; 22-425-02; 22-425-03; 22-425-04; 22-430-33; 22-430-43; 22-430-48; 22-430-53; 22-430-58; 22-430-63; 22-430-67; 22-430-72; 22-430-77; 22-432-30; 22-432-40; 22-432-45; 22-432-50; 22-432-55; 22-432-60; 22-432-65; 22-432-70; 22-732-75; 22-733-30; 22-433-30; 22-433-40; 22-433-45; 22-433-50; 22-433-55; 22-433-60; 22-433-65; 22-433-70; 22-433-75; 22-435-30; 22-435-40; 22-435-45; 22-435-50; 22-435-55; 22-435-60; 22-435-65; 22-435-70; 22-435-75; 22-456-02; 22-456-04; 22-456-06.

Espéculos para ojos

26-430-03; 26-430-04; 26-432-04; 26-436-07; 26-438-07; 26-440-07; 26-440-09; 26-442-06; 26-446-07; 26-448-08; 26-450-08; 26-452-07; 26-452-09; 26-454-07; 26-454-09; 26-456-08 ; 26-460-08; 26-462-07; 26-462-08; 26-466-08; 26-468-08; 26-470-08; 26-474-07; 26-476-07; 26-478-05; 26-480-04; 26-480-05; 26-484-05; 26-484-07; 26-486-07; 26-488-07; 26-500-05; 26-500-07; 26-504-03; 26-508-08; 26-510-07; 26-514-07; 26-518-04; 26-520-03; 26-524-16; 26-528-14.

Espéculos nasales

23-101-01; 23-101-02; 23-101-03; 23-105-01; 23-105-02; 23-105-03; 23-109-01; 23-109-02; 23-109-03; 23-112-13; 23-113-13; 23-116-01; 23-116-02; 23-120-01; 23-120-02; 23-120-03; 23-120-04; 23-122-14; 23-125-01; 23-125-02; 23-127-01; 23-127-02; 23-127-03; 23-127-04; 23-131-01; 23-131-02; 23-131-03; 23-131-04; 23-134-01; 23-134-02; 23-134-03; 23-137-01; 23-137-02; 23-137-03. -

Espéculos rectales

18-701-15; 18-703-15; 18-707-22; 18-713-19; 18-725-06; 18-725-08; 18-725-12; 18-725-15; 18-731-21; 18-735-15; 18-780-13.

Taladros de mano quirúrgicos

13-180-01; 13-180-02; 13-180-03; 13-180-04; 13-180-05; 13-180-06; 13-180-07; 13-180-08; 13-181-00; 13-180-09; 13-180-27; 13-182-00; 13-182-10; 13-184-01; 13-184-02; 13-184-03; 13-186-01; 13-186-02; 13-186-03; 13-186-04; 13-186-05; 13-186-06; 13-186-07; 13-186-09; 13-186-10;

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Gubias

13-322-09; 13-322-14; 13-322-19; 13-322-25; 13-323-09; 13-323-14; 13-323-19; 13-323-25; 13-490-01; 13-490-02; 13-490-03; 13-490-04; 13-490-05; 13-490-06; 13-490-10; 13-490-20; 13-490-30; 13-490-40; 13-492-01; 13-492-02; 13-492-03; 13-492-04; 13-492-10; 13-500-30; 13-500-20; 13-500-10; 13-501-01; 13-501-02; 13-501-03; 13-501-04; 13-502-10; 13-502-20; 13-502-30; 13-502-40; 13-503-01; 13-503-02; 13-503-04; 13-503-05; 13-503-06; 13-504-10; 13-504-20; 13-504-30; 13-504-40; 13-505-01; 13-505-02; 13-505-03; 13-505-04; 13-505-05; 13-505-06; 13-506-10; 13-506-20; 13-506-30; 13-506-40; 13-507-01; 13-507-02; 13-507-03; 13-507-04; 13-507-05; 13-510-10; 13-510-20; 13-511-01; 13-511-02; 13-512-10; 13-512-20; 13-513-01; 13-513-02; 13-514-10; 13-514-20; 13-514-30; 13-515-01; 13-515-02; 13-515-03; 13-515-04; 13-515-05; 13-515-06; 13-516-25; 13-517-25; 13-519-25; 13-520-00; 13-521-00; 13-522-00; 13-523-00; 13-524-00; 13-524-01; 13-524-02; 13-524-03; 13-524-04; 13-524-05; 13-524-06; 13-525-00; 13-525-01; 13-525-02; 13-525-03; 13-525-04; 13-525-05; 13-525-06; 13-527-01; 13-527-02; 13-528-10; 13-528-20; 13-529-01; 13-529-02; 13-530-00; 13-530-01; 13-530-02; 13-530-03; 13-531-00; 13-531-01; 13-531-02; 13-531-03; 13-534-00; 13-534-01; 13-534-02; 13-534-03; 13-534-04; 13-534-05; 13-534-06; 13-534-07; 13-534-08; 13-536-00; 13-536-01; 13-536-02; 13-536-03; 13-536-04; 13-536-05; 13-536-06; 13-536-07; 13-536-08; 13-538-00; 13-538-01; 13-538-02; 13-538-03; 13-538-04; 13-538-05; 13-538-06; 13-538-07; 13-538-08; 13-540-01; 13-540-02; 13-540-03; 13-540-04; 13-540-05; 13-540-06; 13-542-01; 13-542-02; 13-542-03; 13-542-04; 13-542-05; 13-542-06; 13-543-01; 13-543-02; 13-543-03; 13-543-04; 13-543-05; 13-543-06; 13-545-01; 13-545-02; 13-545-03; 13-545-04; 13-545-05; 13-545-06; 13-548-01; 13-548-02; 13-548-03; 13-550-01; 13-550-12; 13-552-00; 13-552-01; 13-552-12; 13-556-16; 13-557-15; 13-560-21; 13-564-13; 13-564-14; 13-564-17; 13-568-13; 13-568-16; 13-568-20; 13-569-18; 13-570-15; 13-571-15; 13-572-01; 13-572-02; 13-572-03; 13-573-01; 13-573-02; 13-573-03; 13-574-01; 13-574-02; 13-574-03; 13-336-06; 13-336-13; 13-336-19; 13-336-25; 13-336-32; 13-337-06; 13-337-13; 13-337-19; 13-337-25; 13-337-32.

Guías de taladro

33-100-00; 33-110-00; 33-120-00; 33-130-15; 33-130-25; 33-130-35; 33-150-11; 33-150-15; 33-150-20; 33-150-25; 33-150-27; 33-150-32; 33-150-35; 33-150-45; 33-150-60; 33-156-15; 33-156-20; 33-156-27; 33-156-35; 33-156-45; 33-156-65; 33-600-02; 33-610-07; 33-620-11; 33-620-20; 33-620-32; 33-624-45; 33-650-27; 33-650-35; 33-650-45; 33-660-11; 33-660-15; 33-666-20; 33-740-45; 33-744-45; 33-748-35; 33-752-27; 33-752-35; 33-756-45; 33-760-32; 33-764-40; 33-764-60; 33-780-45; 33-784-32; 33-790-25; 33-794-32; 33-800-20.

Cucharas para cálculos biliares

19-300-01; 19-300-02; 19-300-03; 19-300-04; 19-300-05; 19-300-06; 19-300-07; 19-300-08; 19-310-01; 19-310-02; 19-310-03; 19-310-04.

Composición cuali-cuanti porcentual exacta (si corresponde):

N/A

Indicación/es autorizada/s:

USO EN CIRUGÍA GENERAL

Período de vida útil (si corresponde):

5 AÑOS

Método de Esterilización (si corresponde):

N/A

Forma de presentación:

ENVASE UNITARIO.

Condición de venta:

Venta Exclusiva a Profesionales e Instituciones Sanitarias

Nombre del fabricante:

TRIMED (PVT) LTD

Lugar/es de elaboración:

4,5Km from Sialkot Dry Port Round About, Airport PK-51070 Road, Sambrial PAKISTAN

En nombre y representación de la firma INSTRUEQUIPOS S.A. , el responsable legal y el responsable técnico declaran bajo juramento que los productos médicos enumerados en el presente Anexo, satisfacen los Requisitos Esenciales de Seguridad y Eficacia (R.E.S.E.) previstos por la Disposición ANMAT N° 4306/99, que cumplen y se encuentra a disposición de la Autoridad Sanitaria la documentación técnica que contenga los requerimientos solicitados en los Anexos III.B y III.C del Reglamento Técnico aprobado por Disposición ANMAT N° 2318/02 (TO 2004) y Disposición ANMAT N° 727/13.

CUMPLIMIENTO DE R.E.S.E. DISPOSICIÓN ANMAT N° 4306/99 Y GESTIÓN DE RIESGO

ENSAYO/VALIDACION/GESTION DE RIESGO	LABORATORIO/N° DE PROTOCOLO	FECHA DE EMISIÓN
N/A	N/A	N/A

El responsable legal y su responsable técnico son responsables de la veracidad de la documentación e información presentada y declaran bajo juramento mantener en su establecimiento y a disposición de la autoridad sanitaria la documentación allí declarada y la que establece la Disposición 727/13, bajo apercibimiento de lo que establece la Ley N° 16.463, el Decreto N° 341/92 y las que correspondan del Código Penal en caso de falsedad.

En caso de inexactitud o falsedad de la información o documentación, la Administración Nacional

podrá suspender, cancelar, prohibir la comercialización y solicitar retiro del mercado de lo ya autorizado e iniciar los sumarios que pudieran corresponder.

LUGAR Y FECHA: Argentina, 02 agosto 2019

Responsable Legal
Firma y Sello

Responsable Técnico
Firma y Sello



Ministerio de Salud
Secretaría de Regulación y Gestión Sanitaria
A.N.M.A.T.

La presente DECLARACIÓN DE CONFORMIDAD ha sido emitida de acuerdo con las previsiones de la Disposición ANMAT N° 727/13 y N°5706/17, quedando inscripta la reválida en el Registro Nacional de Productores y Productos de Tecnología Médica (R.P.P.T.M.) a favor de **INSTRUEQUIPOS S.A.** bajo el número PM **108-117** en la Ciudad de Buenos Aires a los días 02 agosto 2019

La cual tendrá una vigencia de cinco (5) años a partir de la vigencia de la inscripción inicial a través de la Declaración revisión 00, Disposición Autorizante o de sus sucesivas reválidas.

Dirección de Evaluación de Registro

Dirección Nacional de Productos Médicos

Firma y Sello

Firma y Sello



Tramitada por Expediente N°: 1-0047-3110-001568-19-8