

DECLARACIÓN DE AGRUPACIÓN DECLARATION OF SYSTEM PACK

AGRUPADOR / PACKER:

ORDISI, S.A.

DIRECCIÓN / ADDRESS:

Tecnología 2, nave 7-08780 Pallejà, Barcelona, España

SRN:

ES-PR-000000988

DECLARAN BAJO SU EXCLUSIVA RESPONSABILIDAD:

DECLARE UNDER THEIR SOLE RESPONSIBILITY:

Nombre/Name

ASPIRATOR SERIES PACK

Device Nomenclature (EMDN) : Z120105 SURGICAL MEDICAL ASPIRATORS

- LA VERIFICACIÓN DE LA COMPATIBILIDAD MÚTUA DE LOS PRODUCTOS AGRUPADOS, DE ACUERDO CON LAS INSTRUCCIONES DE LOS FABRICANTES, ACTUANDO CON ARREGLO A DICHAS INSTRUCCIONES.
THE VERIFICATION OF THE MUTUAL COMPATIBILITY OF THE PACKED PRODUCTS, IN ACCORDANCE WITH THE INSTRUCTIONS OF THE MANUFACTURERS, ACTING IN ACCORDANCE WITH THESE INSTRUCTIONS.
- EL EMBALAJE DE LA AGRUPACIÓN Y LA FACILITACIÓN DE LA CORRESPONDIENTE INFORMACIÓN A LOS USUARIOS, INCORPORANDO LA INFORMACIÓN SUMINISTRADA POR LOS FABRICANTES DE LOS DIVERSOS PRODUCTOS AGRUPADOS.
THE PACKAGING OF THE PACK AND THE FACILITATION OF THE CORRESPONDING INFORMATION TO THE USERS, INCORPORATING THE INFORMATION SUPPLIED BY THE MANUFACTURERS OF THE VARIOUS PACKED PRODUCTS
- EL CONTROL INTERNO, LA VERIFICACIÓN Y VALIDACIÓN DE LA COMBINACIÓN DE LOS PRODUCTOS COMO SISTEMA PARA PROCEDIMIENTOS.
INTERNAL CONTROL, VERIFICATION AND VALIDATION OF THE COMBINATION OF PRODUCTS AS A SYSTEM FOR PROCEDURES.

La presente declaración se refiere a las siguientes configuraciones / This declaration refers to the following configurations:

COMPONENT #1	COMPONENT #2	COMPONENT #3	COMPONENT #4	System Pack Identifier
ASPIRADOR ASPIRATOR REF: FV-1202SM ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-194 s/REF: 6HAF02-K-HF HUM GmbH CE0197	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe) CE0197	CÁNULA DE ASPIRACIÓN ASPIRATION CANNULA REF: US0104001 s/REF: 643516 Shanghai International Holding Corp. GmbH(Europe) CE0197	REF: FV-1202SM.
ASPIRADOR ASPIRATOR REF: FV-1220SM ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-194 s/REF: 6HAF02-K-HF HUM GmbH CE0197	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe) CE0197	CÁNULA DE ASPIRACIÓN ASPIRATION CANNULA REF: US0104001 s/REF: 643516 Shanghai International Holding Corp. GmbH(Europe) CE0197	REF: FV-1220SM.
ASPIRADOR ASPIRATOR REF: FV-1240SM ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-194 s/REF: 6HAF02-K-HF HUM GmbH CE0197	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe) CE0197	CÁNULA DE ASPIRACIÓN ASPIRATION CANNULA REF: US0104001 s/REF: 643516 Shanghai International Holding Corp. GmbH(Europe) CE0197	REF: FV-1240SM.
ASPIRADOR ASPIRATOR REF: FV-1303SM ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-194 s/REF: 6HAF02-K-HF HUM GmbH CE0197	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe) CE0197	CÁNULA DE ASPIRACIÓN ASPIRATION CANNULA REF: US0104001 s/REF: 643516 Shanghai International Holding Corp. GmbH(Europe) CE0197	REF: FV-1303SM.

ASPIRADOR ASPIRATOR REF: FV-1321SM ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-194 s/REF: 6HAF02-K-HF HUM GmbH CE0197	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe) CE0197	CÁNULA DE ASPIRACIÓN ASPIRATION CANNULA REF: US0104001 s/REF: 643516 Shanghai International Holding Corp. GmbH(Europe) CE0197	REF: FV-1321SM.
ASPIRADOR ASPIRATOR REF: FV-1202SH ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-194 s/REF: 6HAF02-K-HF HUM GmbH CE0197	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe) CE0197	CÁNULA DE ASPIRACIÓN ASPIRATION CANNULA REF: US0104001 s/REF: 643516 Shanghai International Holding Corp. GmbH(Europe) CE0197	REF: FV-1202SH.
ASPIRADOR ASPIRATOR REF: FV-1220SH ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-194 s/REF: 6HAF02-K-HF HUM GmbH CE0197	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe) CE0197	CÁNULA DE ASPIRACIÓN ASPIRATION CANNULA REF: US0104001 s/REF: 643516 Shanghai International Holding Corp. GmbH(Europe) CE0197	REF: FV-1220SH.
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ASPIRADOR ASPIRATOR REF: ASPIT ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-193A s/REF: HAF02-K HUM GmbH CE0197	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe) CE0197	SONDA DE ASPIRACIÓN SUCTION PROBE REF: US0214001 s/REF: 03135B-14 IZASA HOSPITAL, S.L.U CE0044	REF: ASPIT.
ASPIRADOR ASPIRATOR REF: AI-78 ORDISI S.A. CE0051	FILTRO BACTERICIDA BACTERICIDAL TUBE REF: FB-193A s/REF: HAF02-K HUM GmbH	TUBO ASPIRACIÓN ASPIRATION TUBE REF: US0110002 s/REF: 630301 Shanghai International Holding Corp. GmbH(Europe)	SONDA DE ASPIRACIÓN SUCTION PROBE REF: US0214001 s/REF: 03135B-14 IZASA HOSPITAL, S.L.U CE0044	REF: AI-78.

	CE0197	CE0197		
Finalidad Prevista La Aspirator Series es una familia de aspiradores de quirófano y aspiradores portátiles con succión continua o intermitente destinados a vaciar una zona de fluidos corporales durante cirugía mayor, cirugía media, aspiración endoscópica, aspiración ginecológica, aspiración de quirófano o aspiración gástrica. Está destinado a ser utilizado en pacientes que necesitan la extracción de fluidos corporales (sangre, plasma, fluidos intestinales, orina, saliva, etc....) por profesionales de la salud en quirófanos, UCI, UCI móviles y salas de tratamiento. INTENDED USE: <i>The Aspirator Series is a family of operating room aspirators and portable aspirators with continuous or intermittent suction intended to empty a zone from body fluids during major surgery, medium surgery, endoscopic aspiration, gynecological aspiration, operating room aspiration or gastric aspiration. It is intended to be used in patients who need the extraction of corporal fluids (blood, plasma, intestinal fluids, urine, saliva, etc....) by healthcare professionals in Operating rooms, ICUs, mobile ICUs, and treatment rooms.</i> Sistema de Calidad según/ Quality System according: EN ISO 13485:2016/A11:2021; EN ISO 9001:2015				
LUGAR Y FECHA / Place and date: Pallejà 22/11/2024				
Nombre y Firma <i>Name and Signature</i>	  ORDISI Tecnologia, 2 , nau 7 08780 , Pallejà Barcelona, Spain ES-A08258642 			
Rev.4	Marc Pallarès Técnico Responsable/ Compliance Manager		Joan B.Boix Director General/ General Manager	