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EC Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the legal manufacturer.

Name of Products:	Surgical Packs, Sterile
Product Codes:	See **Attachment A**
UMDNS Code:	N/A
GMDN Code:	33961: Sterile Surgical Packs- General surgical procedure kit, non-medicated, single-use
CND Code:	T0201: Surgical Drapes
Legal Manufacturer (Place of Issue):	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 United States of America
Manufacturer SRN :	N/A
Authorized Representative:	ArcRoyal Virginia Road Kells, Co Meath, Ireland
AR SRN: **UDI-DI: (device level)**	IE-AR-000003110 06806517SP010SDP
Start of CE:	23 March 2015
Conformity Assessment Route:	Annex IX, Chapters I and III of Regulation (EU) 2017/745
Risk Classification, Rules:	Class Is per Rule 4, Annex VIII Regulation (EU) 2017/745
CE certificate number:	MDR 739585
Notified Body:	BSI-NL (2797)

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Quality System Certificate:	FM 697013

COMMON SPECIFICATIONS: **NOT APPLICABLE**

STATEMENT: I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of Regulation (EU) 2017/745 concerning Medical Devices.

All supporting documentation that contains proof of compliance to the aforementioned Regulation(s) is retained under the premises of O&M Halyard, Inc. This declaration applies to all devices on the attached product list from the signature date forward.

Authorized Signature:

On behalf of O&M Halyard, Inc

Name: Steven Dowdley
Title: Director, Regulatory Affairs
Address: O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116
United States of America

Date: 13 October 2021

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ATTACHMENT A: Product Codes and Descriptions for Sterile Surgical Packs

Global SKU	Product Description	UDI-DI
29248	Check U and Bar Drape Pack	06806517SP010SDP
29249	Shoulder Split Pack	06806517SP010SDP
29252	PICC Full Body Coverage Pack	06806517SP010SDP
35677	Ophthalmic Pack without Mayo Stand Cover	06806517SP010SDP
48755	Hip Pack I	06806517SP010SDP
48756	Knee Pack I	06806517SP010SDP
48757	Knee Pack II	06806517SP010SDP
48758	Hip Pack	06806517SP010SDP
59704	C-Section Pack	06806517SP010SDP
59706	Lower Extremity Pack	06806517SP010SDP
59707	Hand Pack	06806517SP010SDP
59708	Arthroscopy Pack	06806517SP010SDP
59709	Vein Stripping Pack	06806517SP010SDP
76209	ENT Pack V – Head and Neck	06806517SP010SDP
76216	Laparoscopy Pack	06806517SP010SDP
76226	Hand Pack I	06806517SP010SDP
76234	Plastic Head Pack	06806517SP010SDP
76243	Small Surgical Drape Pack	06806517SP010SDP
76246	Lower Extremity Pack	06806517SP010SDP
76248	Dilation Pack	06806517SP010SDP
76249	Hip Pack	06806517SP010SDP
76250	Neurology Pack	06806517SP010SDP
76251	Neurology Pack	06806517SP010SDP
76263	Universal Laparoscopy Peviscopy Pack	06806517SP010SDP
76271	Hip Pack I	06806517SP010SDP
76276	Basic Pack	06806517SP010SDP
77454	C-Section Pack I	06806517SP010SDP
77455	C-Section Pack II	06806517SP010SDP
77491	C-Section Pack IV	06806517SP010SDP
77492	C-Section Pack V	06806517SP010SDP
77717	Small Procedure Pack II	06806517SP010SDP
77744	Eye Pack	06806517SP010SDP
77748	Cardiovascular Pack II	06806517SP010SDP
77749	Cardiovascular Split Pack	06806517SP010SDP
77760	Ophthalmic Pack	06806517SP010SDP
77762	CV Drape Pack	06806517SP010SDP
77765	Hip Pack IV	06806517SP010SDP

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77766	Abscess Pack	06806517SP010SDP
77769	U-Bar* Pack VII	06806517SP010SDP
77771	Cardiovascular Pack VI	06806517SP010SDP
77772	Universal Pack IV	06806517SP010SDP
77779	Lithotomy Pack IV	06806517SP010SDP
77780	Bilateral Vein Stripping Pack	06806517SP010SDP
77781	Upper Extremity Pack	06806517SP010SDP
77783	Hand Pack	06806517SP010SDP
77784	Knee Pack	06806517SP010SDP
77785	Knee Pack II	06806517SP010SDP
77790	Lower Extremity Pack I	06806517SP010SDP
77792	Laparoscopy/Pelviscopy Pack V	06806517SP010SDP
77794	U-Bar* Pack VI	06806517SP010SDP
77797	Hip Pack	06806517SP010SDP
77798	Lower Extremity Pack II	06806517SP010SDP
77823	ENT Pack IV	06806517SP010SDP
77853	Universal U-Bar* Pack	06806517SP010SDP
77865	Gynecology Pack	06806517SP010SDP
77870	Pace Maker Pack	06806517SP010SDP
77879	Angiography Pack	06806517SP010SDP
77880	Universal Pack XI	06806517SP010SDP
77881	Arthroscopy Pack II	06806517SP010SDP
77888	Gynecology/Urology Pack I	06806517SP010SDP
77890	Gynecology/Urology Pack II	06806517SP010SDP
77892	Cardiovascular Pack III	06806517SP010SDP
88088	Laparoscopy Pack I	06806517SP010SDP
88100	Universal Pack	06806517SP010SDP
88103	Universal Pack	06806517SP010SDP
88113	Basic Pack VIII	06806517SP010SDP
88151	Basic Pack V	06806517SP010SDP
88161	Basic Pack VI	06806517SP010SDP
88171	Set-Up Pack I	06806517SP010SDP
88178	Basic Pack XV	06806517SP010SDP
88183	ORHTOARTS* Hip Pack	06806517SP010SDP
88203	Ortho Pack VII	06806517SP010SDP
88213	ORHTOARTS* Arthroscopy Pack II	06806517SP010SDP
88222	Laparotomy/Pelviscopy Pack	06806517SP010SDP
88223	ENT Pack III	06806517SP010SDP
88231	Laparotomy Pack III	06806517SP010SDP
88233	ORTHOARTS* U-Bar* Pack	06806517SP010SDP
88243	ORTHOARTS* Shoulder Pack II	06806517SP010SDP

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88253	ORTHOARTS* Hip Pack II	06806517SP010SDP
88321	U-BAR* Pack II	06806517SP010SDP
88331	U-BAR* Pack III - Chest	06806517SP010SDP
88334	U-Bar* Pack	06806517SP010SDP
88354	C-Section Pack with Attached Leggings	06806517SP010SDP
88363	Laparoscopy Pelviscopy Pack III	06806517SP010SDP
88373	Ortho Pack III – Major	06806517SP010SDP
88411	Ortho Pack I – Major	06806517SP010SDP
88431	Ortho Pack III – Lower Extremity	06806517SP010SDP
88451	Ortho Pack V – Hip	06806517SP010SDP
88452	ORTHOARTS* Hip Pack with Pockets	06806517SP010SDP
88453	ORTHOARTS* Hip Pack	06806517SP010SDP
88461	Ortho Pack VI- Lower Extremity	06806517SP010SDP
88471	ORTHOARTS* Lower Extremity Pack	06806517SP010SDP
88511	Lithotomy Pack I	06806517SP010SDP
88521	Lithotomy Pack II	06806517SP010SDP
88551	Lithotomy Pack V	06806517SP010SDP
88611	Cystoscopy Pack I	06806517SP010SDP
88621	Cystoscopy Pack II	06806517SP010SDP
88706	Ophthalmic Pack with Mayo Stand Cover	06806517SP010SDP
88711	EENT Pack I	06806517SP010SDP
88716	EENT Pack II	06806517SP010SDP
88719	EENT Pack IV	06806517SP010SDP
88726	C-Section Fluid Collection Pack I	06806517SP010SDP
88759	Universal Pack – Major with Long Side Drapes	06806517SP010SDP
88760	Universal Pack Plus	06806517SP010SDP
88761	Universal Pack I	06806517SP010SDP
88762	Universal Pack, Small	06806517SP010SDP
88763	Universal Pack, Small	06806517SP010SDP
88764	Universal Pack, Large	06806517SP010SDP
88765	Universal Pack, Large	06806517SP010SDP
88767	Universal Pack Plus	06806517SP010SDP
88769	Universal Pack – Minor with Short Side Drapes	06806517SP010SDP
88770	Universal Pack V	06806517SP010SDP
88772	Universal Pack III with Gowns	06806517SP010SDP
88773	U-BAR* Pack IV	06806517SP010SDP
88774	Universal Pack III with Medium Side Drapes	06806517SP010SDP
88781	U-BAR* Pack VI	06806517SP010SDP
88782	Universal Pack VI	06806517SP010SDP
88900	BASICS* Universal Pack I	06806517SP010SDP
88901	BASICS* Universal Pack II	06806517SP010SDP

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88902	BASICS* U-Bar* Pack I	06806517SP010SDP
88904	BASICS* U-Bar* Pack III	06806517SP010SDP
88907	BASICS* Arthroscopic Cruciate Ligament Pack	06806517SP010SDP
88908	BASICS* Shoulder Arthroscopy Pack	06806517SP010SDP
88909	BASICS* Hand & Foot Pack	06806517SP010SDP
88910	BASICS* Hand Pack	06806517SP010SDP
88911	BASICS* Delivery Pack	06806517SP010SDP
89490	2 Piece Shoulder Arthroscopy Drape Pack	06806517SP010SDP
89681	BASICS* Cystoscopy Pack	06806517SP010SDP
89684	BASICS* Extremity Pack	06806517SP010SDP
89686	BASICS* Small Procedure Pack II	06806517SP010SDP
89687	BASICS* Hand Pack II	06806517SP010SDP

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Překlad z anglického jazyka

ES Prohlášení o shodě

Za vydání tohoto prohlášení o shodě nese výhradní odpovědnost oprávněný výrobce.

Název výrobků:	Chirurgické sady, sterilní
Kódy výrobků:	Viz Příloha A
Kód UMDNS:	Nevztahuje se
Kód GMDN:	33961: Sterilní chirurgické sady – Sada pro všeobecné chirurgické výkony, bez léčivých látek, na jedno použití
Kód CND:	T0201: Chirurgické roušky
Oprávněný výrobce (Místo vydání):	O&M Halyard, Inc. 9120 Lockwood Blvd. Mechanicsville, Virginia (VA) 23116 Spojené státy americké
Výr. č. výrobce:	Nevztahuje se
Zmocněný zástupce:	ArcRoyal Virginia Road Kells, Co Meath, Irsko
AC SRN: **UDI-DI: (úroveň prostředku)**	IE-AR-000003110 06806517SP010SDP
Začátek značení CE:	23. března 2015
Postup posouzení shody:	Příloha IX, Kapitola I a III Nařízení (EU) 2017/745
Klasifikace rizika, pravidla:	Třída Is dle pravidla 4, Příloha VIII Nařízení (EU) 2017/745
Číslo certifikátu CE:	MDR 739585
Notifikovaná osoba:	BSI-NL (2797)

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Certifikát systému jakosti:	FM 697013

SPOLEČNÉ SPECIFIKACE: NEVZTAHUJÍ SE

PROHLÁŠENÍ: Já, níže podepsaný, tímto prohlašuji, že uvedený zdravotnický prostředek splňuje / uvedené zdravotnické prostředky splňují příslušná ustanovení Nařízení (EU) 2017/745 o zdravotnických prostředcích.

Veškerá podpůrná dokumentace, která obsahuje doklady o shodě s výše uvedenými nařízeními, je uchovávána v prostorách společnosti O&M Halyard, Inc. Toto prohlášení platí pro všechny prostředky na připojeném seznamu výrobků ode dne podpisu dále.

Podpis zplnomocněné osoby:

nečitelné

Za společnost O&M Halyard, Inc

Jméno: Steven Dowdley
Funkce: ředitel pro regulatorní záležitosti
Adresa: O&M Halyard, Inc.
9120 Lockwood Blvd.
Mechanicsville, Virginia (VA) 23116
Spojené státy americké

Datum: 13. října 2021

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PŘÍLOHA A: Kódy a názvy výrobků pro sterilní chirurgické sady

Globální č. objednací	Název výrobku	UDI-DI
29248	Check U and Bar Drape Pack	06806517SP010SDP
29249	Shoulder Split Pack	06806517SP010SDP
29252	PICC Full Body Coverage Pack	06806517SP010SDP
35677	Ophthalmic Pack without Mayo Stand Cover	06806517SP010SDP
48755	Hip Pack I	06806517SP010SDP
48756	Knee Pack I	06806517SP010SDP
48757	Knee Pack II	06806517SP010SDP
48758	Hip Pack	06806517SP010SDP
59704	C-Section Pack	06806517SP010SDP
59706	Lower Extremity Pack	06806517SP010SDP
59707	Hand Pack	06806517SP010SDP
59708	Arthroscopy Pack	06806517SP010SDP
59709	Vein Stripping Pack	06806517SP010SDP
76209	ENT Pack V – Head and Neck	06806517SP010SDP
76216	Laparoscopy Pack	06806517SP010SDP
76226	Hand Pack I	06806517SP010SDP
76234	Plastic Head Pack	06806517SP010SDP
76243	Small Surgical Drape Pack	06806517SP010SDP
76246	Lower Extremity Pack	06806517SP010SDP
76248	Dilation Pack	06806517SP010SDP
76249	Hip Pack	06806517SP010SDP
76250	Neurology Pack	06806517SP010SDP
76251	Neurology Pack	06806517SP010SDP
76263	Universal Laparoscopy Peviscopy Pack	06806517SP010SDP
76271	Hip Pack I	06806517SP010SDP
76276	Basic Pack	06806517SP010SDP
77454	C-Section Pack I	06806517SP010SDP
77455	C-Section Pack II	06806517SP010SDP
77491	C-Section Pack IV	06806517SP010SDP
77492	C-Section Pack V	06806517SP010SDP
77717	Small Procedure Pack II	06806517SP010SDP
77744	Eye Pack	06806517SP010SDP
77748	Cardiovascular Pack II	06806517SP010SDP
77749	Cardiovascular Split Pack	06806517SP010SDP
77760	Ophthalmic Pack	06806517SP010SDP
77762	CV Drape Pack	06806517SP010SDP
77765	Hip Pack IV	06806517SP010SDP

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77766	Abscess Pack	06806517SP010SDP
77769	U-Bar* Pack VII	06806517SP010SDP
77771	Cardiovascular Pack VI	06806517SP010SDP
77772	Universal Pack IV	06806517SP010SDP
77779	Lithotomy Pack IV	06806517SP010SDP
77780	Bilateral Vein Stripping Pack	06806517SP010SDP
77781	Upper Extremity Pack	06806517SP010SDP
77783	Hand Pack	06806517SP010SDP
77784	Knee Pack	06806517SP010SDP
77785	Knee Pack II	06806517SP010SDP
77790	Lower Extremity Pack I	06806517SP010SDP
77792	Laparoscopy/Pelviscopy Pack V	06806517SP010SDP
77794	U-Bar* Pack VI	06806517SP010SDP
77797	Hip Pack	06806517SP010SDP
77798	Lower Extremity Pack II	06806517SP010SDP
77823	ENT Pack IV	06806517SP010SDP
77853	Universal U-Bar* Pack	06806517SP010SDP
77865	Gynecology Pack	06806517SP010SDP
77870	Pace Maker Pack	06806517SP010SDP
77879	Angiography Pack	06806517SP010SDP
77880	Universal Pack XI	06806517SP010SDP
77881	Arthroscopy Pack II	06806517SP010SDP
77888	Gynecology/Urology Pack I	06806517SP010SDP
77890	Gynecology/Urology Pack II	06806517SP010SDP
77892	Cardiovascular Pack III	06806517SP010SDP
88088	Laparoscopy Pack I	06806517SP010SDP
88100	Universal Pack	06806517SP010SDP
88103	Universal Pack	06806517SP010SDP
88113	Basic Pack VIII	06806517SP010SDP
88151	Basic Pack V	06806517SP010SDP
88161	Basic Pack VI	06806517SP010SDP
88171	Set-Up Pack I	06806517SP010SDP
88178	Basic Pack XV	06806517SP010SDP
88183	ORHTOARTS* Hip Pack	06806517SP010SDP
88203	Ortho Pack VII	06806517SP010SDP
88213	ORHTOARTS* Arthroscopy Pack II	06806517SP010SDP
88222	Laparotomy/Pelviscopy Pack	06806517SP010SDP
88223	ENT Pack III	06806517SP010SDP
88231	Laparotomy Pack III	06806517SP010SDP
88233	ORTHOARTS* U-Bar* Pack	06806517SP010SDP
88243	ORTHOARTS* Shoulder Pack II	06806517SP010SDP

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88253	ORTHOARTS* Hip Pack II	06806517SP010SDP
88321	U-BAR* Pack II	06806517SP010SDP
88331	U-BAR* Pack III - Chest	06806517SP010SDP
88334	U-Bar* Pack	06806517SP010SDP
88354	C-Section Pack with Attached Leggings	06806517SP010SDP
88363	Laparoscopy Pelviscopy Pack III	06806517SP010SDP
88373	Ortho Pack III – Major	06806517SP010SDP
88411	Ortho Pack I – Major	06806517SP010SDP
88431	Ortho Pack III – Lower Extremity	06806517SP010SDP
88451	Ortho Pack V – Hip	06806517SP010SDP
88452	ORTHOARTS* Hip Pack with Pockets	06806517SP010SDP
88453	ORTHOARTS* Hip Pack	06806517SP010SDP
88461	Ortho Pack VI- Lower Extremity	06806517SP010SDP
88471	ORTHOARTS* Lower Extremity Pack	06806517SP010SDP
88511	Lithotomy Pack I	06806517SP010SDP
88521	Lithotomy Pack II	06806517SP010SDP
88551	Lithotomy Pack V	06806517SP010SDP
88611	Cystoscopy Pack I	06806517SP010SDP
88621	Cystoscopy Pack II	06806517SP010SDP
88706	Ophthalmic Pack with Mayo Stand Cover	06806517SP010SDP
88711	EENT Pack I	06806517SP010SDP
88716	EENT Pack II	06806517SP010SDP
88719	EENT Pack IV	06806517SP010SDP
88726	C-Section Fluid Collection Pack I	06806517SP010SDP
88759	Universal Pack – Major with Long Side Drapes	06806517SP010SDP
88760	Universal Pack Plus	06806517SP010SDP
88761	Universal Pack I	06806517SP010SDP
88762	Universal Pack, Small	06806517SP010SDP
88763	Universal Pack, Small	06806517SP010SDP
88764	Universal Pack, Large	06806517SP010SDP
88765	Universal Pack, Large	06806517SP010SDP
88767	Universal Pack Plus	06806517SP010SDP
88769	Universal Pack – Minor with Short Side Drapes	06806517SP010SDP
88770	Universal Pack V	06806517SP010SDP
88772	Universal Pack III with Gowns	06806517SP010SDP
88773	U-BAR* Pack IV	06806517SP010SDP
88774	Universal Pack III with Medium Side Drapes	06806517SP010SDP
88781	U-BAR* Pack VI	06806517SP010SDP
88782	Universal Pack VI	06806517SP010SDP
88900	BASICS* Universal Pack I	06806517SP010SDP
88901	BASICS* Universal Pack II	06806517SP010SDP

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88902	BASICS* U-Bar* Pack I	06806517SP010SDP
88904	BASICS* U-Bar* Pack III	06806517SP010SDP
88907	BASICS* Arthroscopic Cruciate Ligament Pack	06806517SP010SDP
88908	BASICS* Shoulder Arthroscopy Pack	06806517SP010SDP
88909	BASICS* Hand & Foot Pack	06806517SP010SDP
88910	BASICS* Hand Pack	06806517SP010SDP
88911	BASICS* Delivery Pack	06806517SP010SDP
89490	2 Piece Shoulder Arthroscopy Drape Pack	06806517SP010SDP
89681	BASICS* Cystoscopy Pack	06806517SP010SDP
89684	BASICS* Extremity Pack	06806517SP010SDP
89686	BASICS* Small Procedure Pack II	06806517SP010SDP
89687	BASICS* Hand Pack II	06806517SP010SDP

PŘEKLADATELSKÁ DOLOŽKA

Já, Mgr. Alice Tejkalová, jsem provedla překladatelský úkon jako tlumočnice a překladatelka jmenovaná podle zákona č. 36/1967 Sb. rozhodnutím předsedy Krajského soudu v Praze ze dne 15. listopadu 1991, č.j. Spr. 698/91, pro jazyk český a anglický, zapsaná v seznamu soudních tlumočníků a soudních překladatelů vedeném Ministerstvem spravedlnosti ČR, v souladu s § 44 zákona č. 354/2019 Sb., o soudních tlumočnících a soudních překladatelích.
Stvrzuji, že překlad souhlasí s textem připojené listiny.

Úkon je zapsán v evidenci úkonů pod číslem 7905/2022 dne 19.05.2022.

Translator´s Clause

I, Mgr. Alice Tejkalová, translated the document as an interpreter and translator to English appointed by the decision of the Regional Court in Prague on November 15, 1991, file. No. Spr. 698/91, under Act No. 36/1967 Sb., and entered in the Register of Court Interpreters and Court Translators maintained by the Ministry of Justice of the Czech Republic in compliance with Act No. 354/2019 Sb., on Court Interpreters and Court Translators, Section 44.
I hereby certify that this is a true and accurate translation of the original document.

The translation is entered in the translation register under No. 7905/2022 on 19.05.2022.

Mgr. Alice Tejkalová

Mgr. Alice Tejkalová

Mgr. Alice TEJKALOVÁ
soudní překladatel jazyka anglického a českého