

EC Declaration of Conformity

Name of Products: Surgical Packs

Product Codes: See **Attachment A**

UMDNS Code: 15646 (Drapes, Surgical, Disposable)

GMDN Code: 33961 (Sterile Surgical Packs-General surgical procedure kit, non-medicated, single-use)

Legal Manufacturer (Place of Issue): Halyard Health, Inc.
5405 Windward Parkway
Alpharetta, Georgia (GA) 30004, USA

EC Authorized Representative: Halyard Belgium BVBA
Leonardo Da Vincilaan 1
1930 Zaventem
Belgium

Product Standards: BS EN 13795:2011

Start of CE: See **Attachment A**

Conformity Assessment Route: Annex V (for sterile surgical packs)
Annex VII (for non-sterile surgical packs)

Device Classification, Rules: Class I and Class I Sterile, Rule 1 per Annex IX

CE certificate number: CE 621867 (for sterile surgical packs only)

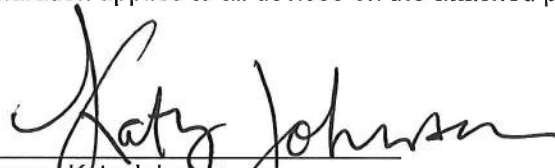
Notified Body: BSI (0086) (for sterile surgical packs only)

EC Quality System Certificate: FM 620884 (BSI)

I, the undersigned, hereby declare that the specified medical device(s) meet(s) the applicable provisions of European Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.

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

Authorized Signature:



Name: Katy Johnson
Title: Regulatory Affairs Technical Leader
Halyard Health, Inc.
Date: 22-May-2015

Attachment A (Product List)

This attachment specifies the products included in the above referenced Declaration of Conformity.

Product Code	Product Description	Sterilization	Start of CE Mark
29249	Shoulder Split Pack	Sterile-EO	23-Mar-2015
29250	CVC Full Body Coverage Pack	Sterile-EO	23-Mar-2015
29251NS	CVC Full Body Coverage Pack (Gown, Full Coverage CVC Drape, Bouffant, Facemask - wrapped in CSR)	Non-Sterile	09-Dec-2014
29252	PICC Full Body Coverage Pack	Sterile-EO	23-Mar-2015
29253NS	PICC Full Body Coverage Pack	Non-Sterile	09-Dec-2014
59704	C-Section Pack	Sterile-EO	23-Mar-2015
59706	Lower Extremity Pack	Sterile-EO	23-Mar-2015
59707	Hand Pack	Sterile-EO	23-Mar-2015
59708	Arthroscopy Pack	Sterile-EO	23-Mar-2015
59709	Vein Stripping Pack	Sterile-EO	23-Mar-2015
76209	ENT Pack V - Head and Neck	Sterile-EO	23-Mar-2015
76216	Laparoscopy Pack	Sterile-EO	23-Mar-2015
76218	Laparoscopy Pelviscopy Pack	Sterile-EO	23-Mar-2015
76219	Cardiovascular Pack	Sterile-EO	23-Mar-2015
76226	Hand Pack I	Sterile-EO	23-Mar-2015
76234	Plastic Head Pack	Sterile-EO	23-Mar-2015
76240	Surgical Gown Pack	Sterile-EO	23-Mar-2015
76242	Universal Pack	Sterile-EO	23-Mar-2015
76243	Small Surgical Drape Pack	Sterile-EO	23-Mar-2015
76246	Lower Extremity Pack	Sterile-EO	23-Mar-2015
76248	Dilatation Pack	Sterile-EO	23-Mar-2015
76249	Hip Pack	Sterile-EO	23-Mar-2015
76250	Neurology Pack	Sterile-EO	23-Mar-2015
76251	Neurology Pack	Sterile-EO	23-Mar-2015
76263	Universal Laparoscopy Pelviscopy Pack	Sterile-EO	23-Mar-2015
76271	Hip Pack I	Sterile-EO	23-Mar-2015
76276	Basic Pack	Sterile-EO	23-Mar-2015
77454	C-Section Pack I	Sterile-EO	23-Mar-2015
77455	C-Section Pack II	Sterile-EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
77456	Gown Pack I	Sterile-EO	23-Mar-2015
77458	4 Gown Pack	Sterile-EO	23-Mar-2015
77491	C-Section Pack IV	Sterile-EO	23-Mar-2015
77492	C-Section Pack V	Sterile-EO	23-Mar-2015
77717	Small Procedure Pack II	Sterile-EO	23-Mar-2015
77719	C-Section Pack	Sterile-EO	23-Mar-2015
77729	U-BAR* Pack VIII	Sterile-EO	23-Mar-2015
77744	Eye Pack	Sterile-EO	23-Mar-2015
77748	Cardiovascular Pack II	Sterile-EO	23-Mar-2015
77749	Cardiovascular Split Pack	Sterile-EO	23-Mar-2015
77760	Ophthalmic Pack	Sterile-EO	23-Mar-2015
77762	CV Drape Pack	Sterile-EO	23-Mar-2015
77765	Hip Pack IV	Sterile-EO	23-Mar-2015
77766	Abscess Pack	Sterile-EO	23-Mar-2015
77769	U-BAR* Pack VII	Sterile-EO	23-Mar-2015
77771	Cardiovascular Pack VI	Sterile-EO	23-Mar-2015
77772	Universal Pack IV	Sterile-EO	23-Mar-2015
77779	Lithotomy Pack IV	Sterile-EO	23-Mar-2015
77780	Bilateral Vein Stripping Pack	Sterile-EO	23-Mar-2015
77781	Upper Extremity Pack	Sterile-EO	23-Mar-2015
77783	Hand Pack	Sterile-EO	23-Mar-2015
77784	Knee Pack I	Sterile-EO	23-Mar-2015
77785	Knee Pack II	Sterile-EO	23-Mar-2015
77787	Urology Pack	Sterile-EO	23-Mar-2015
77790	Lower Extremity Pack I	Sterile-EO	23-Mar-2015
77792	Laparoscopy/Pelviscopy Pack V	Sterile-EO	23-Mar-2015
77794	U-BAR* Pack VI	Sterile-EO	23-Mar-2015
77797	Hip Pack	Sterile-EO	23-Mar-2015
77798	Lower Extremity Pack II	Sterile-EO	23-Mar-2015
77823	ENT Pack IV	Sterile-EO	23-Mar-2015
77835	Maxillo - Facial Pack	Sterile-EO	23-Mar-2015
77853	Universal U-BAR* Pack	Sterile-EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
77865	Gynaecology Pack	Sterile-EO	23-Mar-2015
77870	Pace Maker Pack	Sterile-EO	23-Mar-2015
77879	Angiography Pack	Sterile-EO	23-Mar-2015
77880	Universal Pack XI	Sterile-EO	23-Mar-2015
77881	Arthroscopy Pack II	Sterile-EO	23-Mar-2015
77885	T.U.R. Pack	Sterile-EO	23-Mar-2015
77888	Gynaecology/Urology Pack I	Sterile-EO	23-Mar-2015
77890	Gynaecology/Urology Pack II	Sterile-EO	23-Mar-2015
77892	Cardiovascular Pack III	Sterile-EO	23-Mar-2015
88088	Laparoscopy Pack I	Sterile-EO	23-Mar-2015
88100	Universal Pack	Sterile-EO	23-Mar-2015
88103	Universal Pack	Sterile-EO	23-Mar-2015
88113	Basic Pack VIII	Sterile-EO	23-Mar-2015
88151	Basic Pack V	Sterile-EO	23-Mar-2015
88161	Basic Pack VI	Sterile-EO	23-Mar-2015
88171	Set-Up Pack I	Sterile-EO	23-Mar-2015
88178	Basic Pack XV	Sterile-EO	23-Mar-2015
88183	ORTHOARTS* Hip Pack	Sterile-EO	23-Mar-2015
88203	Ortho Pack VII	Sterile-EO	23-Mar-2015
88213	ORTHOARTS* Arthroscopy Pack II	Sterile-EO	23-Mar-2015
88222	Laparoscopy/Pelviscopy Pack	Sterile-EO	23-Mar-2015
88223	ENT Pack III	Sterile-EO	23-Mar-2015
88231	Laparotomy Pack III	Sterile-EO	23-Mar-2015
88233	ORTHOARTS* U-BAR* Pack	Sterile-EO	23-Mar-2015
88243	ORTHOARTS* Shoulder Pack II	Sterile-EO	23-Mar-2015
88253	ORTHOARTS* Hip Pack II	Sterile-EO	23-Mar-2015
88321	U-Bar* Pack II	Sterile-EO	23-Mar-2015
88331	U-BAR* Pack III – Chest	Sterile-EO	23-Mar-2015
88334	U-BAR* Pack	Sterile-EO	23-Mar-2015
88354	C-Section Pack with Attached Leggings	Sterile-EO	23-Mar-2015
88363	Laparoscopy Pelviscopy Pack III	Sterile-EO	23-Mar-2015
88373	Ortho Major Pack III	Sterile-EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
88411	Ortho Pack I – Major	Sterile-EO	23-Mar-2015
88431	Ortho Pack III - Lower Extremity	Sterile-EO	23-Mar-2015
88451	Ortho Pack V – Hip	Sterile-EO	23-Mar-2015
88452	ORTHOARTS* Hip Pack with Pockets	Sterile-EO	23-Mar-2015
88453	ORTHOARTS* Hip Pack	Sterile-EO	23-Mar-2015
88461	Ortho Pack VI Lower Extremity	Sterile-EO	23-Mar-2015
88471	ORTHOARTS* Lower Extremity Pack	Sterile-EO	23-Mar-2015
88511	Lithotomy Pack I	Sterile-EO	23-Mar-2015
88521	Lithotomy Pack II	Sterile-EO	23-Mar-2015
88531	Lithotomy Pack III	Sterile-EO	23-Mar-2015
88551	Lithotomy Pack V	Sterile-EO	23-Mar-2015
88611	Cystoscopy Pack I	Sterile-EO	23-Mar-2015
88621	Cystoscopy Pack II	Sterile-EO	23-Mar-2015
88706	Ophthalmic Pack with Mayo Stand Cover	Sterile-EO	23-Mar-2015
88711	EENT Pack I	Sterile-EO	23-Mar-2015
88716	EENT Pack II	Sterile-EO	23-Mar-2015
88718	OCUARTS* Ophthalmic Pack	Sterile-EO	23-Mar-2015
88719	EENT Pack IV	Sterile-EO	23-Mar-2015
88726	C-Section Fluid Collection Pack I	Sterile-EO	23-Mar-2015
88759	Universal Pack - Major with Long Side Drapes	Sterile-EO	23-Mar-2015
88760	Universal Pack Plus	Sterile-EO	23-Mar-2015
88761	Universal Pack I	Sterile-EO	23-Mar-2015
88762	Universal Pack, Small	Sterile-EO	23-Mar-2015
88763	Universal Pack, Small	Sterile-EO	23-Mar-2015
88764	Universal Pack, Large	Sterile-EO	23-Mar-2015
88765	Universal Pack, Large	Sterile-EO	23-Mar-2015
88767	Universal Pack Plus	Sterile-EO	23-Mar-2015
88769	Universal Pack - Minor with Short Side Drapes	Sterile-EO	23-Mar-2015
88770	Universal Pack V	Sterile-EO	23-Mar-2015
88772	Universal Pack III with Gowns	Sterile-EO	23-Mar-2015
88773	U-Bar* Pack IV	Sterile-EO	23-Mar-2015
88774	Universal Pack III with Medium Side Drapes	Sterile-EO	23-Mar-2015

Product Code	Product Description	Sterilization	Start of CE Mark
88781	U-BAR* Pack VI	Sterile-EO	23-Mar-2015
88782	Universal Pack IV	Sterile-EO	23-Mar-2015
88900	HALYARD BASICS* Universal Pack I	Sterile-EO	23-Mar-2015
88901	HALYARD BASICS* Universal Pack II	Sterile-EO	23-Mar-2015
88902	HALYARD BASICS* U-Bar Pack I	Sterile-EO	23-Mar-2015
88903	HALYARD BASICS* U-Bar Pack II	Sterile-EO	23-Mar-2015
88904	HALYARD BASICS* U-Bar Pack III	Sterile-EO	23-Mar-2015
88905	HALYARD BASICS* U-Bar Pack IV	Sterile-EO	23-Mar-2015
88906	HALYARD BASICS* Small Procedure Pack	Sterile-EO	23-Mar-2015
88907	HALYARD BASICS* Arthroscopic Cruciate Ligament (ACL) Pack	Sterile-EO	23-Mar-2015
88908	HALYARD BASICS* Shoulder Arthroscopy Pack with MSC	Sterile-EO	23-Mar-2015
88909	HALYARD BASICS* Hand & Foot Pack	Sterile-EO	23-Mar-2015
88910	HALYARD BASICS* Hand Pack	Sterile-EO	23-Mar-2015
88911	HALYARD BASICS* Delivery Pack	Sterile-EO	23-Mar-2015
89681	HALYARD BASICS* Cystoscopy Pack	Sterile-EO	23-Mar-2015
89682	HALYARD BASICS* Basic Pack	Sterile-EO	23-Mar-2015
89684	HALYARD BASICS* Extremity Pack	Sterile-EO	23-Mar-2015
89685	HALYARD BASICS* Hand & Foot Pack II	Sterile-EO	23-Mar-2015
89686	HALYARD BASICS* Small Procedure Pack II	Sterile-EO	23-Mar-2015
89687	HALYARD BASICS* Hand Pack II	Sterile-EO	23-Mar-2015