Change Notification

CC-21-0447

Transfer of data from user manual of LIFE 21 apheresis unit to package inserts of adsorbers

Product	REF
330-000-621	LIFE 21 apheresis unit (purchase)
330-000-622	LIFE 21 apheresis unit (rental)
330-000-795	TheraSorb - Ig omni 5
330-000-793	TheraSorb - Ig omni 1
330-000-792	TheraSorb - LDL
330-000-551	TheraSorb - LDL pro
330-000-573	TheraSorb - IgE

Category of change: Change of package inserts

Current State: The ”LIFE 21 apheresis unit Adsorption therapies – Appendix: Adsorber and process specifications” user manual contains adsorber-specific product descriptions as well as treatment parameters, e.g., solution volumes during treatment, reinfusion and preservation, plasma loading cycles, number of cycles etc.. In addition, it contains general paragraphs and information that are is present in other user manuals and package inserts of the TheraSorb LIFE 21 product line, and therefore redundant.

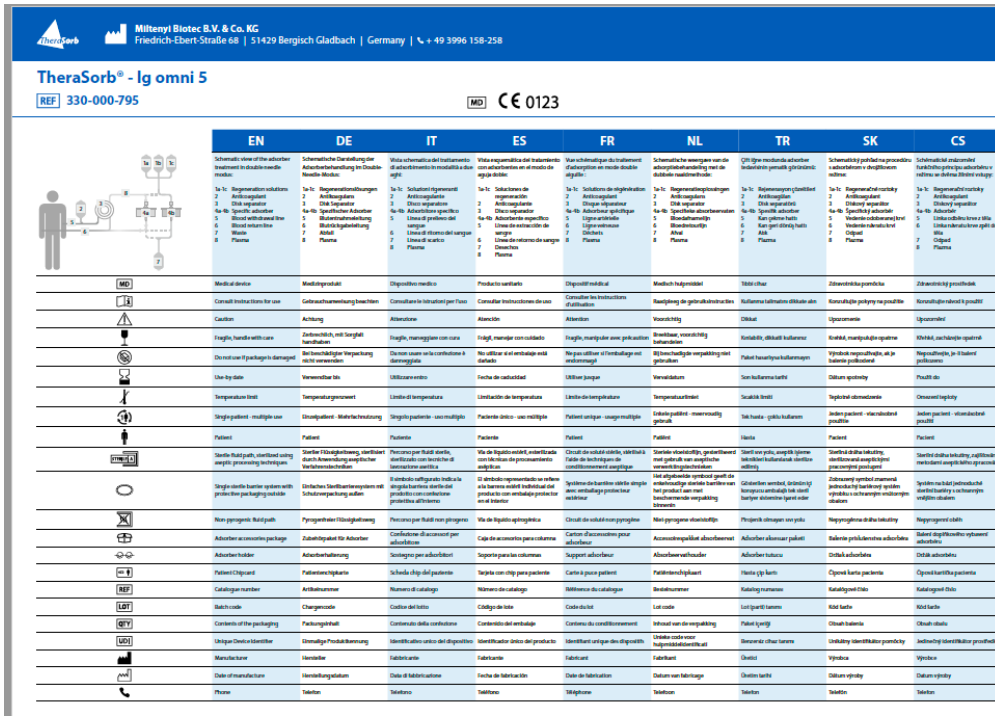
Planned change: Essential information from the LIFE 21 user manual “Appendix: Adsorber and process specifications” shall be transferred to the respective adsorber package inserts. The content shall be placed in a tabular form, on a

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separate page of the package insert, similar to the glossary section (depicted below).



Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Straße 68 | 51429 Bergisch Gladbach | Germany | + 49 3996 158-258

TheraSorb® - Ig omni 5

REF 330-000-795

MD CE 0123

EN	DE	IT	ES	FR	NL	TR	SK	CS
Medical device	Medizinprodukt	Dispositivo medico	Producto sanitario	Dispositif médical	Medisch hulpmiddel	Tıbbi cihaz	Zdravotnícka pomôcka	Zdravotnický prostředek
Caution	Achtung	Attenzione	Atención	Attention	Voorzichtig	Dikkat	Upozornenie	Upozornění
Do not use if package is damaged	Bei beschädigter Verpackung nicht verwenden	Da non usare se la confezione è danneggiata	No utilizar si el embalaje está dañado	Ne pas utiliser si l'emballage est endommagé	Bij beschadigde verpakking niet gebruiken	Paket hasarlıysa kullanmayın	Výrobok nepoužívajte, ak je balenie poškodené	Nepoužívejte, je-li balení poškozeno
Use-by date	Verwendbar bis	Utilizzare entro	Fecha de caducidad	Utiliser jusque	Verwaldatum	Son kullanma tarihi	Dátum spotreby	Použít do
Temperature limit	Temperaturgrenzwert	Limite di temperatura	Limitación de temperatura	Limite de température	Temperatuurlimiet	Sıcaklık limiti	Teplotné obmedzenie	Omezení teploty
Single-patient - multiple use	Einzelpatient - Mehrfachnutzung	Singolo paziente - uso multiplo	Paciente único - uso múltiple	Patient unique - usage multiple	Enkele patiënt - meervoudig gebruik	Tek hasta - çoklu kullanım	Jeden pacient - viacnásobné použitie	Jeden pacient - vícenásobné použití
Patient	Patient	Paziente	Paciente	Patient	Patiënt	Hasta	Pacient	Pacient
Sterile fluid path, sterilized using aseptic processing techniques	Steriler Flüssigkeitsweg, sterilisiert durch Anwendung aseptischer Verfahrenstechniken	Percorso per fluidi sterile, sterilizzato con tecniche di lavorazione asettica	Vía de líquido estéril, esterilizada con técnicas de procesamiento aséptico	Circuit de soluté stérile, stérilisé à l'aide de techniques de conditionnement aseptique	Steriele vloeistofpijn, gesteriliseerd met gebruik van aseptische verwerkingstechnieken	Steril sıvı yolu, aseptik işleme teknikleri kullanılarak sterilize edilmiş	Sterilná dráha tekutiny, sterilizovaná aseptickými postupmi	Sterilní dráha tekutiny, sterilizovaná aseptickými postupy
Single-sterile barrier system with protective packaging outside	Einfaches Sterilbarrieresystem mit Schutzverpackung außen	Il simbolo raffigurato indica la singola barriera sterile del prodotto con confezione protettiva all'esterno	El símbolo representado se refiere a la barrera estéril individual del producto con embalaje protector en el interior	Système de barrière stérile simple avec emballage protecteur extérieur	Het afgebeelde symbool geeft de enkelvoudige steriele barrière van het product aan met beschermende verpakking binnenin	Görüntülen sembol, ürünün iç koruyucu ambalajlı tek steril bariyer sistemine işaret eder	Zobrazený symbol znamená jednoduchý bariérový systém výrobku s ochranným vnútorným obalom	Znázorněný symbol znamená jednoduchý bariérový systém výrobku s ochranným vnějším obalem
Non-pyrogenic fluid path	Pyrogenfreier Flüssigkeitsweg	Percorso per fluidi non pirogeno	Vía de líquido apirogénica	Circuit de soluté non pyrogène	Niet-pyrogene vloeistofpijn	Pirojenik olmayan sıvı yolu	Nepyrogénna dráha tekutiny	Nepyrogenní oběh
Adsorber accessories package	Zubehörpaket für Adsorber	Confezione di accessori per adsorbitore	Caja de accesorios para columna	Carton d'accessoires pour adsorbeur	Accessoirespakket absorbeerder	Adsorber aksesuar paketi	Balenie príslušenstva adsorbéra	Balení doplňkového vybavení adsorbéru
Adsorber holder	Adsorberhalterung	Sostegno per adsorbitori	Soporte para las columnas	Support adsorbeur	Absorbeerderhouder	Adsorber tutucu	Držiak adsorbéra	Držák adsorbéru
Patient Chipcard	Patientenchipkarte	Scheda chip del paziente	Tarjeta con chip para paciente	Carte à puce patient	Patiëntenchipkaart	Hasta çip kartı	Čipová karta pacienta	Čipová karta pacienta
Catalogue number	Artikelnummer	Numero di catalogo	Número de catálogo	Référence du catalogue	Bestelnummer	Katalog numarası	Katalógové číslo	Katalogové číslo
Batch code	Chargencode	Codice del lotto	Código de lote	Code du lot	Lot code	Lot (parti) numarası	Kód šarže	Kód šarže
Contents of the packaging	Packungsinhalt	Contenuto della confezione	Contenido del embalaje	Contenu du conditionnement	Inhoud van de verpakking	Paket içeriği	Obsah balenia	Obsah obalu
Unique Device Identifier	Eindeutige Produktkennung	Identificativo unico del dispositivo	Identificador único del producto	Identifiant unique des dispositifs	Unieke code voor hulpmiddelidentificatie	Benzersiz cihaz tanımı	Unikátny identifikátor pomôcky	Jedinečný identifikátor prostředku
Manufacturer	Hersteller	Fabbricante	Fabricante	Fabricant	Fabrikant	Üretici	Výrobca	Výrobce
Date of manufacture	Herstellungsdatum	Data di fabbricazione	Fecha de fabricación	Date de fabrication	Datum van fabricage	Üretim tarihi	Dátum výroby	Datum výroby
Phone	Telefon	Telefono	Teléfono	Téléphone	Telefoon	Telefon	Telefón	Telefon

The user manual becomes obsolete.

Justification/ Evaluation: The planned change is acceptable as important process specifications will remain part of the labelling, and only be transferred to the adsorbers' package inserts. In contrast, redundant pieces of information will be eliminated from the labelling making it clearer.
There is no change of raw material or manufacturing process.
Therefore, no impact on the performance, quality and safety of the affected products could be identified.

Estimated Implementation Dec. 2022

Please share, if applicable, this information with relevant staff in your organization.
If there are any further questions, do not hesitate to contact us.

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07.Mar.2022

Manager QA Audit/Customer/Supplier
Miltenyi Biotec B.V. & Co.KG