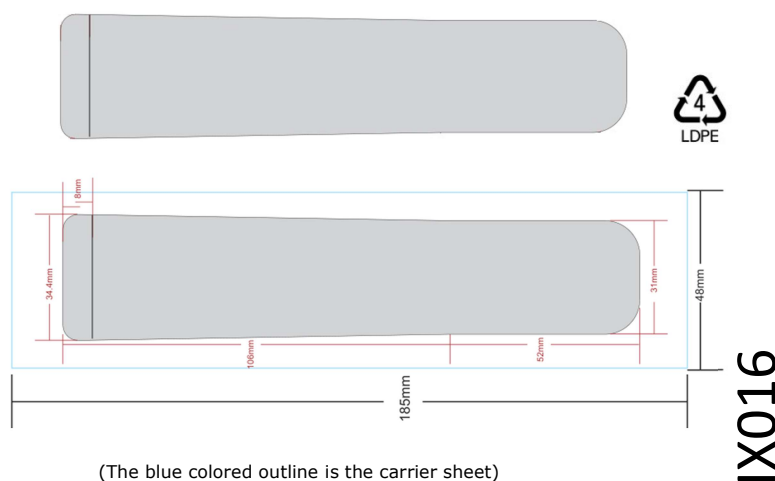


Technical specification sheet - TECHS016SLEEVECD-V3

Date	: Januar 13, 2025*
Product name	: Sensor Sleeve #0
Sheet #	: TECHS016SLEEVECD-V3
Color	: Sleeve: Transparent Carrier: Raw White
Article code	: IX016
UDI	: 8717228440205
Basic UDI-DI	: 871722844SSL1173
General purpose	: hygiene sleeve for sensor **
Technics	: Hot sealing
Material / made off	: Sleeve; LDPE Carrier; White kraft paper, color double side raw white
Certificates/Registrations	: CE : (EU) 2017/ 745 - NL-CA002-2021-62809 DuPhaMed B.V. FDA: 3005739556 / 9087279 / Product Code: EGZ / Listing #: D421812
UK RP	: UKCA Experts Ltd. Dept 302, 43 Owston Road, Carcroft, Doncaster, DN6 8DA, United Kingdom
Classifications	: MDR Class I Risk Class I
Recyclable	: Sleeve: Yes as LDPE ** Carrier: Yes as Paper **
Supplied as	: Refill pack

Images, drawings including dimensions are indicative and not to scale.



(The blue colored outline is the carrier sheet)

*Revisions	Date	description
V2	April 29, 2024	-Material used for Carrier changed to White paper -Adjustment recyclable including adding symbol recyclable code 4 -General hygiene notes
V3	Januari 14, 2025	-Specification of the paper carrier added -New drawing -Adjusting text within, "Application" and "Instructions for using the sleeve" -And added address of the UKRP in this documentation:

Application

The sensor sleeves is to prevent transfer contamination by body fluids and bacteria from one patient to another, by using sensor and sensor holder. Without the need of disinfecting the sensor itself.
The paper carrier enables easy picking out of the box.

Instructions for using the sleeve

Prior to applying the sleeve, remove the paper carrier.
Slide sensor into sleeve, until the end.
Place the sensor/sleeve into the sensor holder.

General hygiene notes

**The sensor sleeve must be used on one patient and after use be handled as separated waste.
Check your local regulations concerning recycling.

General terms

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