

URGENT FIELD SAFETY NOTICE - Annex II Inspection Instruction

Subject: FSCA 745922 - HLS & PLS Set - potentially compromised sterile barrier

Affected Products:

REF no.	Article no.	Product description
BE-PLS 2050	701068386	PLS Set
BE-PLS 2051	701068389	PLS Set Plus
BO-PLS 2051	701068390	HIT Set PLS Plus
BE-PLS 2050	701076706	PLS China
BE-HLS 7050	701069073	HLS Set Advanced 7.0
BE-HLS 5050	701069076	HLS Set Advanced 5.0
BO-HLS 7050	701069083	HIT Set Advanced 7.0
BO-HLS 5050	701069079	HIT Set Advanced 5.0
BEQ-HLS 7050-CA	701069065	HLS Set Advanced 7.0
BEQ-HLS 5050-CA	701069068	HLS Set Advanced 5.0
BEQ-HLS 7050 USA	701069078	HLS Set Advanced 7.0
BEQ-HLS 5050 USA	701069077	HLS Set Advanced 5.0

1. Inspection of Intellipacks (plastic packaging component of the product)

Before use, the holder for safety plates of the Intellipacks must be checked for possible damage.

(In Part 2, example pictures of conform and nonconforming parts are shown for assistance.)



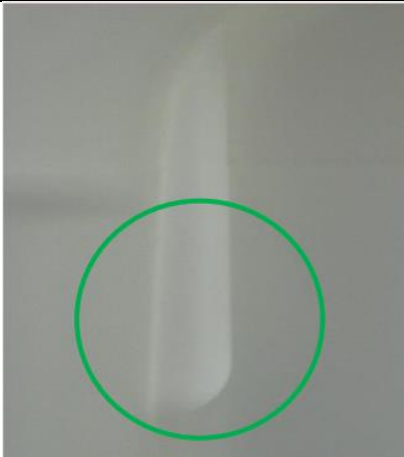

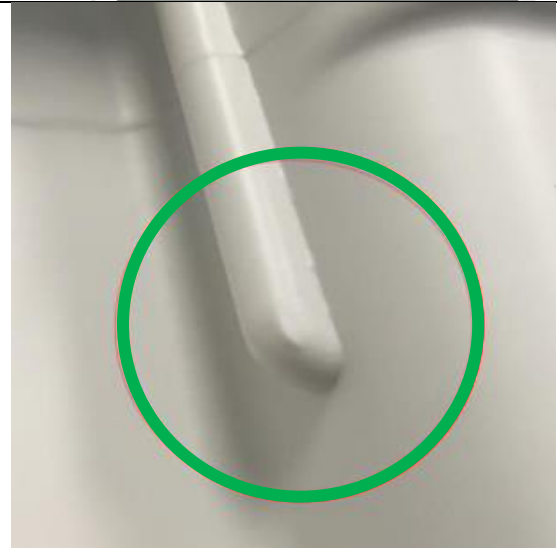
For this purpose, the handles present in the outer packaging must be pressed in. As a result, the holder of the Safety plate is visible on the Intellipack.



Use a commercially available LED flashlight during the investigation to get a better view on the holder of the safety plates!

Note: The holders for the safety plates are only present on one side.



2. Exemplary pictures of conforming and not conforming products	
Material is undamaged (pictures 1 and 2) or shows white stress marks only (picture 3) and can be used	Material is damaged (with a visible breakthrough) and cannot be used
<p>1</p> 	
<p>2</p> 	
<p>3</p> 	

Template: CP-SOP-001-T-02 V02, Effective date 2019-09-15