
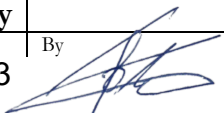


# 300645

## SP-003 Package label specification

|                    |   |
|--------------------|---|
| <b>Document ID</b> | 300645 SP-003 Package label   |
| <b>Version</b>     | 04  |
| <b>Reviewed by</b> |  |
| Date               | 2024-05-23  |
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## Document History

| Version | Date       | Comment   |
|---------|------------|---|
| 01      | 2022-02-09 | Based on 300430.<br>Updated REF from SP-003 to SP003-0001 and SP003-0002 respectively   |
| 02      | 2022-04-05 | JB: Added SP003-0008 and SP003-0009.  |
| 03      | 2022-04-29 | Added symbols for<br><ul style="list-style-type: none"> <li>- Number of units in package</li> <li>- Used by date</li> </ul>                           |
| 04      | 2024-05-14 | HP: Serial number for components and devices of Catalyst+ now indicates if its produced by Innokas or Scanfil.<br><br>Correction to correct material. |

## SP-003 Package Label Specification

The following SP-003 system products exist:

| Catalyst+ System Name    | UDI Number     | REF        |
|--------------------------|----------------|------------|
| Catalyst+                | 17350005280762 | SP003-0001 |
| Catalyst+ HD             | 17350005280779 | SP003-0002 |
| Catalyst+ HD Ring Gantry | 17350005280786 | SP003-0007 |
| Catalyst+ PT             | 17350005280793 | SP003-0008 |
| Catalyst+ PT X4          | 17350005280809 | SP003-0009 |

The package label shall contain the following information (Example labels for both HY-004 and HY-005 packages):

## Catalyst+

Patient positioning system SP-003

(01) 1 7350005 28076 2

(11) YYMMDD

(21) SP-003-nnnnn-XX

1  
 N/A

|            |                   |
|------------|-------------------|
| <b>REF</b> | <b>SP003-0001</b> |
| <b>SN</b>  | SP-003-nnnn-XX    |
| <b>SN</b>  | HY-004.02-ssss-XX |
|            | YYYY-MM-DD        |

C-RAD Positioning AB  
Sjukhusvägen 12K  
SE-753 09 Uppsala  
Sweden  
**Made in Finland**

Rx Only
 

MD

C

E

0123

Figure 1. Label for HY-004 if it forms a Catalyst+ system without side scanners (i.e. NOT as an HD-system).

## Catalyst+ HD

Patient positioning system SP-003

(01) 1 7350005 28077 9

(11) YYMMDD

(21) SP-003-nnnn-XX

1  
 N/A

|            |                   |
|------------|-------------------|
| <b>REF</b> | <b>SP003-0002</b> |
| <b>SN</b>  | SP-003-nnnn-XX    |
| <b>SN</b>  | HY-004.02-ssss-XX |
|            | YYYY-MM-DD        |

C-RAD Positioning AB  
Sjukhusvägen 12K  
SE-753 09 Uppsala  
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Figure 2. Label for HY-004 if it is part of a Catalyst+ HD-system.

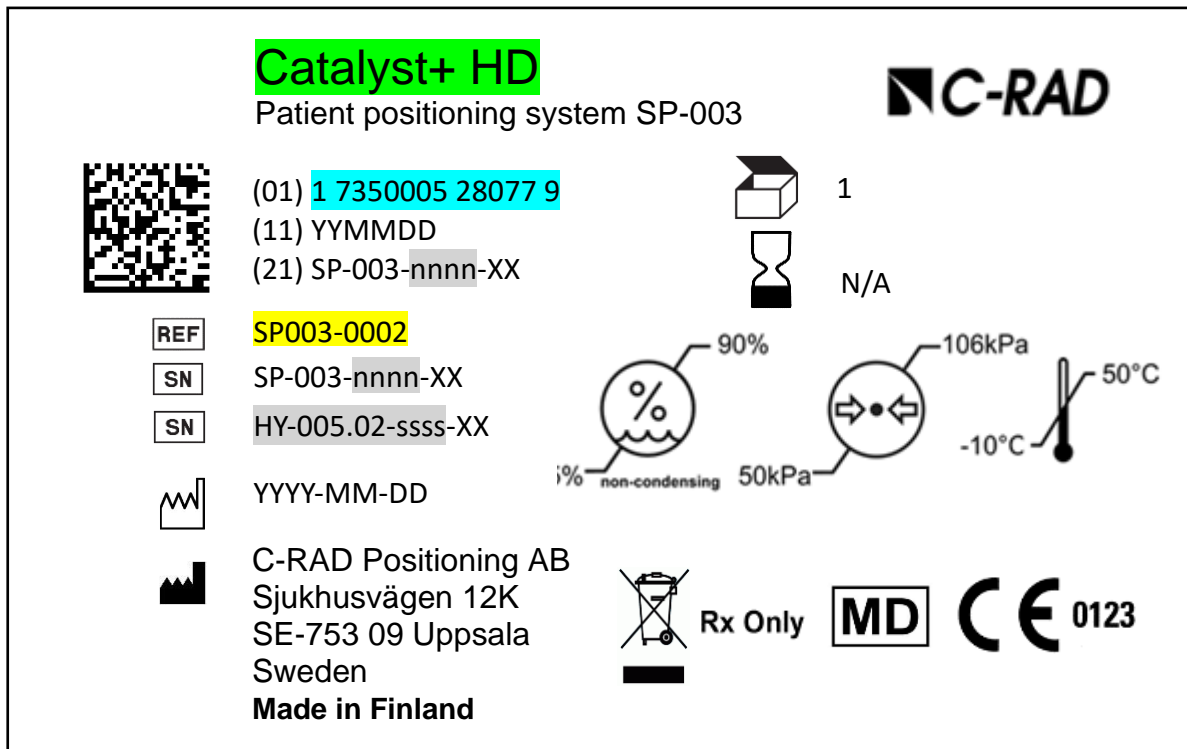


Figure 3. Label for HY-005 as part of a Catalyst+ HD-system.

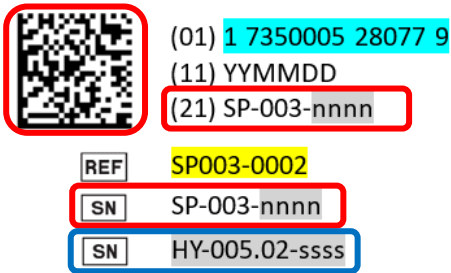
- Update the Catalyst+ System Name, UDI number and Product REF according to the table above.
- Update the Manufacturing date “YYMMDD” and “YYYY-MM-DD”, System serial number “nnnn” and “ssss” and UDI data matrix.
- Update “-XX” with “-SF” only if produced by Scanfil. Otherwise leave blank. Also replace “Made in Finland” with “Made in China”

## Material and color

Material: B-423 (Brady) white glossy (white polyester).  
 Background color: White Glossy  
 Print color: Black  
 Size: 76.2 x 50.8 mm

## System Serial number

The SP-003 System Serial No. shall be the same as the Catalyst+ System product inside the package. The System serial no shall be on the UDI data matrix and on a SN text fields, see the three locations outlined in red below.



## Component Serial number

The Component Serial No. shall be the same as the Catalyst<sup>+</sup> component inside the package. The Component serial no shall be on one SN text field, see location outlined in blue above.

*Example 1:* A package containing a Catalyst<sup>+</sup> Master scanner with serial no. HY-004.02-0218 shall have SP-003 package labelled with Serial No. HY-004.02-0218.

*Example 2:* A package containing a Catalyst<sup>+</sup> Side scanner with serial no. HY-005.02-0104 shall have SP-003 package labelled with Serial No. HY-005.02-0104.

*Example 3:* A package containing a Gating Box with serial no. HZ-009.02-0075 shall have SP-003 package Serial No. HZ-009.02-0075.