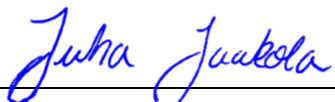



300633

SP-003 System label specification

Document ID	300633
Version	03
Reviewed by	
Date: 2024-05-14	By Juha Jaakola / Supply Chain Engineer
Approved by	
Date: 2024-05-21	By  Thomas Matzen, QA/RA

The information contained in this document is of a proprietary and confidential nature and is intended only for the persons whom it is directly transmitted by C-RAD. Any reproduction of this document in whole or part, or the divulgence of any of its contents without the prior written consent by C-RAD is prohibited. This document is subject to change without notice.

Document History

Version	Date	Comment
01	2022-02-09	ECO-2825.
02	2022-04-05	JB: Added SP003-0008 and SP003-0009.
03	2024-05-14	HP: Serial number for components and devices of Catalyst+ now indicates if its produced by Innokas or Scanfil.

SP-003 System label

The following SP-003 system products exist:

Catalyst+ System Name	UDI Number	REF	System label on
Catalyst+	17350005280762	SP003-0001	HY-004
Catalyst+ HD	17350005280779	SP003-0002	HY-004
Catalyst+ HD Ring Gantry	17350005280786	SP003-0007	HY-004
Catalyst+ PT	17350005280793	SP003-0008	HY-004
Catalyst+ PT X4	17350005280809	SP003-0009	HY-004

The SP-003 System label shall contain the following symbols and text. Text indicated in yellow, green and turquoise shall be selected according to the table above.

Label specification

The label shall contain the symbols and text as presented in Figure 1.

- 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 “SP-003-nnnn” and UDI data matrix.
- Update “-XX” with “-SF” only if produced by Scanfil. Otherwise leave blank.

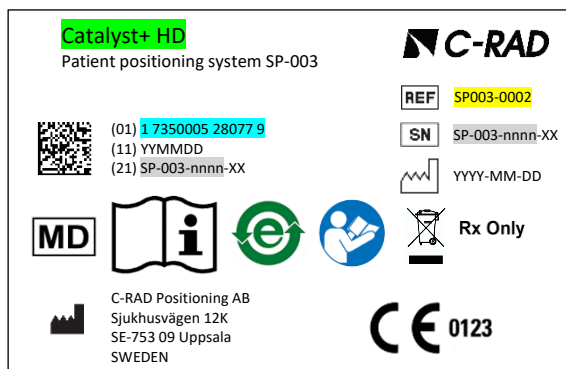


Figure 1. SP-003 System Label example for SP003-0002 Catalyst+ HD.

- Material type: B-423 (Brady) white glossy (white polyester).

- Label width: 76,2 mm; height: 50,8 mm
- For every hundred label delivered take a random selection of two labels, attach them to the enclosure and perform the following tests:
 - The label shall be removable with a tool only or by appreciable force.
 - Rub markings by hand, without pressure, first for 15s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit at ambient temperature and then for 15 s with a cloth rag soaked with isopropyl alcohol. Markings shall be clearly legible after the test.

UDI Number

The UDI number and accompanying data matrix is created by using GS1 elements AI (01), (11) and (21) as described by Table 2. The (11) element matches the production date on the label. The (21) element is identically as the one on the type label indicated by “SN”.

The AI (01) tag is taken from the UDI number column in Table 1.

Table 1 Products and UDI Numbers

Configuration	Product ID	UDI number
Catalyst ⁺	SP003-0001	17350005280762
Catalyst ⁺ HD	SP003-0002	17350005280779
Catalyst ⁺ HD Ring Gantry	SP003-0007	17350005280786
Catalyst+ PT	SP003-0008	17350005280793
Catalyst+ PT X4	SP003-0009	17350005280809

Table 2 GS1 Elements

Table 2-1 GS1 element strings		
AI	Data definition	Format (AI & data)*
01	GTIN	N2+N14
10	Batch or lot number	N2+X..20
11	Production date (YYMMDD)	N2+N6
15	Best before date (YYMMDD)	N2+N6
17	Expiration date (YYMMDD)	N2+N6
21	Serial number	N2+X..20

Table 2-2 * Meaning of the format used	
Format	Meaning
N	Numeric digit
X	Alphanumeric characters
N2	Fixed length of two numeric digits
X..20	Variable length with a maximum of 20 alphanumeric characters

A complete list of Application Identifiers can be found in the GS1 General Specifications.

Data Matrix Quality Measurement

The data matrix print quality shall follow the standard ISO/IEC 15415 Barcode print quality test specification – Two-dimensional symbols.