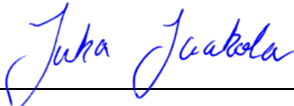



Label additions - China



Document ID	P-181018-001
Version	06
Reviewed	
Date: 2024-05-06	By Juha Jaakola Supply Chain Engineer
Approved	
Date: 2024-05-06	By  Thomas Matzen, QA/RA

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Document history

Version	Date	Author/Comments
01	2018-10-22	JN/ EA 1378 Labels specified for Catalyst & Sentinel packages.
02	2018-10-23	JN/ EA 1378 Removed color from Catalyst label.
03	2020-09-29	JB/ ECO-2520, New head office address
04	2021-07-05	JB, SP-003 labels added
05	2024-02-23	Bob: <ul style="list-style-type: none">- Updated the Sentinel package label to match the information on the renewed NMPA certificate 20233050264 issued in June 2023- Added device label for Sentinel to be placed on the scanner- Added label for Catalyst+/Catalyst+ HD- Deleted Catalyst label
06	Approval date	Bob <ul style="list-style-type: none">- Changed Authorized Representative from CRCS to C-RAD China on labels for Catalyst+- Adjusted label size



SP-001 (Sentinel System) Labels

Label on LS200

For Sentinel shipped to customers in China Mainland an additional product label is required. The additional product label shall contain the following information:

<p>产品名称：放射治疗患者光学定位系统 型号： Sentinel 生产日期： (Production date) 有效期限： 10 年 产品技术要求/注册证编号： 国械注进 20233050264 注册人及生产商 名称： C-RAD Positioning AB 瑞典希迪定位公司 注册人住所： Sjukhusvägen 12k, 753 09 Uppsala, Sweden 生产地址： Vihikari 10, FI- 90440 Kempele, Finland (委托生产)</p> <p>其他内容详见说明书</p>	
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Material: Polyester, White, Glossy, Thermal transfer

Print color: Black

Size: 76.2 x 50.8 mm

Replace (Production date) with date manufactured (format yyyy-mm-dd).



Label on package

For Sentinel packages shipped to Chinese customers an additional label is required. This additional label shall contain the following information:

放射治疗患者光学定位系统	
型号: Sentinel	
注册人/制造商: C-RAD Positioning AB 瑞典希迪定位公司	
注册人住所: Sjukhusvägen 12K, 753 09 Uppsala, SWEDEN	
生产地址: Vihikari 10, FI- 90440 Kempele, Finland (委托生产)	
生产日期: (Production date)	
使用期限: 10 年	
注册证编号: 国械注进 20233050264	
联系方式: info@c-rad.com	
代理人名称: 希迪 (上海) 医疗器械有限公司	
代理人住所: 中国 (上海) 自由贸易试验区盛夏路 608 号 3 幢 211 室	
联系方式: +4618666930	
其他内容详见说明书	

Material: Paper, White, Matte, Thermal transfer

Print color: Black

Size: 150x99mm

Replace (Production date) with date manufactured (format yyyy-mm-dd).



SP-003 (Catalyst+ System) Labels

Label on package and on Device

For Catalyst+ shipped to Chinese customers an additional label is required.

Two identical copies of the label shall be printed:

- One label shall be attached to the HY-004 package
- One label shall be attached to the HY-004 (Master scanner)

This additional label shall contain the following information:

Catalyst+

患者摆位验证装置	
型号: Catalyst+	
注册人/制造商: C-RAD Positioning AB 瑞典希迪定位公司	
注册人住所: Sjukhusvägen 12K, 75309 Uppsala, SWEDEN	
生产地址: Vihikari 10, FI- 90440 Kempele, Finland (委托生产)	
生产日期: (Production date)	
有效期: 10 年	
电源: 100-240VAC, 50/60Hz	
注册证编号: 国械注进 20213050055	
联系方式: info@c-rad.com	
代理人名称: 希迪 (上海) 医疗器械有限公司	
代理人住所: 中国 (上海) 自由贸易试验区盛夏路 608 号 3 幢 211 室	
联系方式: +4618666930	
其他内容详见说明书	



Catalyst+ HD

患者摆位验证装置



型号: Catalyst+ HD

注册人/制造商: C-RAD Positioning AB 瑞典希迪定位公司

注册人住所: Sjukhusvägen 12K, 75309 Uppsala, SWEDEN

生产地址: Vihikari 10, FI- 90440 Kempele, Finland (委托生产)

生产日期: (Production date)

有效期: 10 年

电源: 100-240VAC, 50/60Hz

注册证编号: 国械注进 20213050055

联系方式: info@c-rad.com

代理人名称: 希迪(上海)医疗器械有限公司

代理人住所: 中国(上海)自由贸易试验区盛夏路 608 号 3 幢 211 室

联系方式: +4618666930

其他内容详见说明书



Device label:

Material: Polyester, White, Glossy, Thermal transfer

Print color: Black

Size: 76.2 x 50,8 mm

Package label:

Material: Paper, White, Matte, Thermal transfer

Print color: Black

Size: 150x99mm

Replace (Production date) with date manufactured (format yyyy-mm-dd).