



U.S. Department
of Transportation

Pipeline and
Hazardous Materials
Safety Administration

East Building, PHH-23
1200 New Jersey Ave, SE
Washington, D.C. 20590

**COMPETENT AUTHORITY CERTIFICATION FOR A
TYPE B(U)**

**RADIOACTIVE MATERIALS PACKAGE DESIGN
CERTIFICATE USA/0844/B(U) , REVISION 0**

**REVALIDATION OF UNITED KINGDOM COMPETENT AUTHORITY
CERTIFICATE GB/4120/B(U)**

The Competent Authority of the United States certifies that the radioactive material package design described in this certificate satisfies the regulatory requirements for a Type B(U) package as prescribed in the regulations of the International Atomic Energy Agency¹ and the United States of America² The package design is approved for use within the United States for import and export shipments made in accordance with applicable international and domestic transport regulations.

1. Package Identification - DPR 200.
2. Package Description and Authorized Radioactive Contents - as described in United Kingdom Certificate of Competent Authority GB/4120/B(U) (Rev.0) (attached).
3. General Conditions -
 - a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation. The user shall prepare the package for shipment in accordance with the documentation and applicable regulations.
 - b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Engineering and Research, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.

¹ "Regulations for the Safe Transport of Radioactive Material, 2018 Edition, No. SSR-6" published by the International Atomic Energy Agency (IAEA), Vienna, Austria.

² Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

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- c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.
 - d. Records of Management System activities required by Paragraph 306 of the IAEA regulations¹ shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors in the United States exporting shipments under this certificate shall satisfy the applicable requirements of Subpart H of 10 CFR 71.
4. Marking and Labeling - The package shall bear the marking USA/0844/B(U) in addition to other required markings and labeling.
5. Expiration Date - This certificate expires on March 31, 2027. Previous editions which have not reached their expiration date may continue to be used.

This certificate is issued in accordance with paragraph(s) 810 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the April 26, 2022 petition by STERIS Applied Sterilization Technologies, Madison, OH, and in consideration of other information on file in this Office.

Certified By:



William Schoonover
Associate Administrator for Hazardous
Materials Safety

March 30, 2023
(DATE)

Revision 0 - Issued to revalidate UK Certificate of Competent
Authority GB/4120/B(U) (Rev.0).

CERTIFICATE OF APPROVAL OF PACKAGE DESIGN FOR THE CARRIAGE OF RADIOACTIVE MATERIAL

This is to certify that for the purposes of the Regulations of the International Atomic Energy Agency

- The Competent Authority of Great Britain in respect of inland surface transport, being the Office for Nuclear Regulation;
- The Competent Authority of the United Kingdom of Great Britain and Northern Ireland in respect of sea transport, being the Secretary of State for Transport;
- The Competent Authority of the United Kingdom of Great Britain and Northern Ireland in respect of air transport, being the Civil Aviation Authority; and
- The Competent Authority of Northern Ireland in respect of road transport, being the Department of Agriculture, Environment and Rural Affairs - Northern Ireland

approve the package design specified in Section 1 of this certificate, as submitted for approval by Synergy Health Sterilisation UK Ltd (see Section 5)

as: Type B(U)

by: road and rail in Great Britain; and sea and air.

Packaging identification: DPR 200

Packages manufactured to this design meet the requirements of the regulations and codes on page 2, relevant to the mode of transport, subject to the following general condition and to the conditions in the succeeding pages of this certificate.

In the event of any alteration in the composition of the package, the package design, the management system(s) associated with the package or in any of the facts stated in the application for approval, this certificate will cease to have effect unless the Competent Authority is notified of the alteration and the Competent Authority confirms the certificate notwithstanding the alteration.

Expiry Date: This certificate cancels all previous revisions and is valid until 31 March 2027 (see Section 5).

COMPETENT AUTHORITY IDENTIFICATION MARK: GB/4120/B(U) (Rev.0)

Signature:



Date of Issue: 01 April 2022

Gavin Smith, Superintending Inspector
Office for Nuclear Regulation

Redgrave Court, Merton Road
Bootle, Merseyside
L20 7HS

on behalf of the Office for Nuclear Regulation; the Secretary of State for Transport; the Civil Aviation Authority; and the Department of Agriculture, Environment and Rural Affairs - Northern Ireland.

This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.

REGULATIONS GOVERNING THE TRANSPORT OF RADIOACTIVE MATERIALS

INTERNATIONAL

International Atomic Energy Agency (IAEA)

SSR-6 Regulations for the Safe Transport of Radioactive Material 2018 Edition

United Nations Economic Commission for Europe (UNECE)

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)
2021 Edition

Intergovernmental Organisation for International Carriage by Rail (OTIF)

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)
2021 Edition

International Maritime Organization (IMO)

International Maritime Dangerous Goods (IMDG) Code 2020 Edition incorporating
Amendment 40-20

International Civil Aviation Organization (ICAO)

Technical Instructions for the Safe Transport of Dangerous Goods by Air 2021-2022
Edition

UNITED KINGDOM

ROAD

GREAT BRITAIN ONLY:

The Energy Act 2013 (2013 c. 32); The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No. 1348); The Energy Act 2013 (Office for Nuclear Regulation) (Consequential Amendments, Transitional Provisions and Savings) Order 2014 (SI 2014 No. 469)

NORTHERN IRELAND ONLY:

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010, (SR 2010 No 160)

RAIL

GREAT BRITAIN ONLY:

The Energy Act 2013 (2013 c. 32); The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009 No. 1348); The Energy Act 2013 (Office for Nuclear Regulation) (Consequential Amendments, Transitional Provisions and Savings) Order 2014 (SI 2014 No. 469)

SEA

British registered ships and all other ships whilst in United Kingdom territorial waters:

The Merchant Shipping Act 1995 (1995 c. 21); The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997 (SI 1997 No. 2367); Merchant Shipping Notice MSN 1906 (M) The Carriage of Dangerous Goods and Marine Pollutants: Amendments to

International Standards, Including Amendment 40-20 to the IMDG Code and amendments to the IBC Code and BCH Code

AIR

The Air Navigation Order 2016 (SI 2016 No. 765); The Air Navigation (Dangerous Goods) Regulations 2002 (SI 2002 No.2786)

1. DESIGN SPECIFICATION

Package Design

- 1.1 The package design specification shall be in accordance with 'SR-033: DPR 200 Type B(U) Design Safety Report' (Rev. 1) dated 21 January 2022, and modifications to the package design approved by the authorities named on page 1 of this certificate under the established modifications procedure.

Design Drawings

- 1.2 The design is specified in the following drawings.

Design No.	Title (number of components)	Drawing / Drawing List	Revision
DPR 200	Container Drawings List	SR-001 DPR 200	8
DPR 201	Container Drawings List	SR-001 DPR 201 Basket Drawings List	2

Package Description and Materials of Manufacture

- 1.3 The packaging is a stainless steel, lead shielded, upright, finned cylinder with a conventional plug type closure in the top and thermal insulation built into its upper and lower corners. The impact / thermal shield assembly (cylindrical, insulated jacket and top shield with energy absorbing structures) and the energy absorbing pallet are constructed predominantly from carbon steel. A stainless-steel grill around the top of the jacket restricts access to the flask surface. The closure has a vent point and the cavity has a drain tube to allow the flask to be operated in ponds. The cylindrical cavity holds the encapsulated radioactive material in a basket. Although primarily intended to carry Special Form (SF) capsules, the package has a containment system as it may also be used to carry non-Special Form encapsulated material. The closure and the vent and drain plugs are equipped with testable seals. The top of the drain tube is fitted with a filter and a spring gasket is used to seal the gap under the closure around the top of the cavity. See Appendix 1 for package illustration.

Package Dimension and Weights

- 1.4 Nominal dimensions: 1200 mm square x 1832 mm high
- 1.5 Maximum authorised gross weight: 5220 kg

Authorised Contents

- 1.6 The radioactive content is restricted to a maximum of 0.214 kg of ^{60}Co .
- 1.7 Total activity is limited to:
- 8.51 PBq of Special Form ^{60}Co when transported by road, rail and sea
 - 8.14 PBq of non-Special Form ^{60}Co when transported by road, rail and sea
 - 1.20 PBq of Special Form or non-Special Form ^{60}Co when transported by air

Restriction on Contents

- 1.8 Radioactive content must be loaded into the DPR 201 source basket.

Containment System

- 1.9 The containment system comprises the flask and closure inner surfaces, the closure fixings, the vent and drain plugs and the three inner O-ring seals. There are three removable containment components:
- a. The closure: Retained by eight M20 studs.
 - b. The vent plug: Screwed into the closure.
 - c. The drain plug: Screwed into the side of the flask.

2. USE OF PACKAGE

Information Provided in Safety Report on Use of Packaging

- 2.1 The packaging shall be used and handled in accordance with OP-010 DPR 200 Operating and Maintenance Instructions Rev 4.
- 2.2 The packaging shall be maintained in accordance with OP-010 DPR 200 Operating and Maintenance Instructions Rev 4.

Actions Prior to Shipment

- 2.3 Administrative controls shall ensure that the contents are in accordance with Section 1 of this certificate, and that the consignor and consignee hold a copy of the certificate and instructions on the use of the packaging.
- 2.4 Prior to shipment, the package must be adequately surveyed to ensure that surface dose rates are compliant with routine conditions of transport dose rate criteria.

Supplementary Operational Controls

- 2.5 No supplementary operational controls are required.

Emergency Arrangements

- 2.6 Before shipment takes place, adequate emergency arrangements must be made, copies of which shall be supplied to the GB Competent Authority on demand.
- 2.7 Within Great Britain, if the consignor's own, or other approved emergency plans, cannot be initiated for any reason, then the police shall be informed immediately.

3. MANAGEMENT SYSTEMS

- 3.1 The management system(s) assessed as adequate in relation to this design by the authorities named on page 1 of this certificate, at the date of issue, are as specified in Section 7 of the package design safety report 'SR-033: DPR 200 Type B(U) Design Safety Report' (Rev. 1) dated 21 January 2021, and comprise the following:
- Synergy Health Sterilisation UK Ltd, Isotope Services Quality Management System

- 3.2 No alteration may be made to any management system confirmed as adequate in relation to this design, unless:
- a) the authorities named on page 1 of this certificate have confirmed the amended management system is adequate prior to implementation or use; or
 - b) the alteration falls within the agreed change control procedures set out in the management system(s).
- 3.3 Other management systems for design, testing, manufacture, documentation, use, maintenance, inspection, transport and in-transit storage operations may be used providing they comply with international, national or other standards for management systems agreed as acceptable by the authorities named on page 1 of this certificate.

4. ADMINISTRATIVE INFORMATION

Packaging Serial Numbers

- 4.1 For the purpose of compliance with ADR / RID, the owner of the packaging shall be responsible for informing ONR of the serial number of each packaging manufactured to this design.

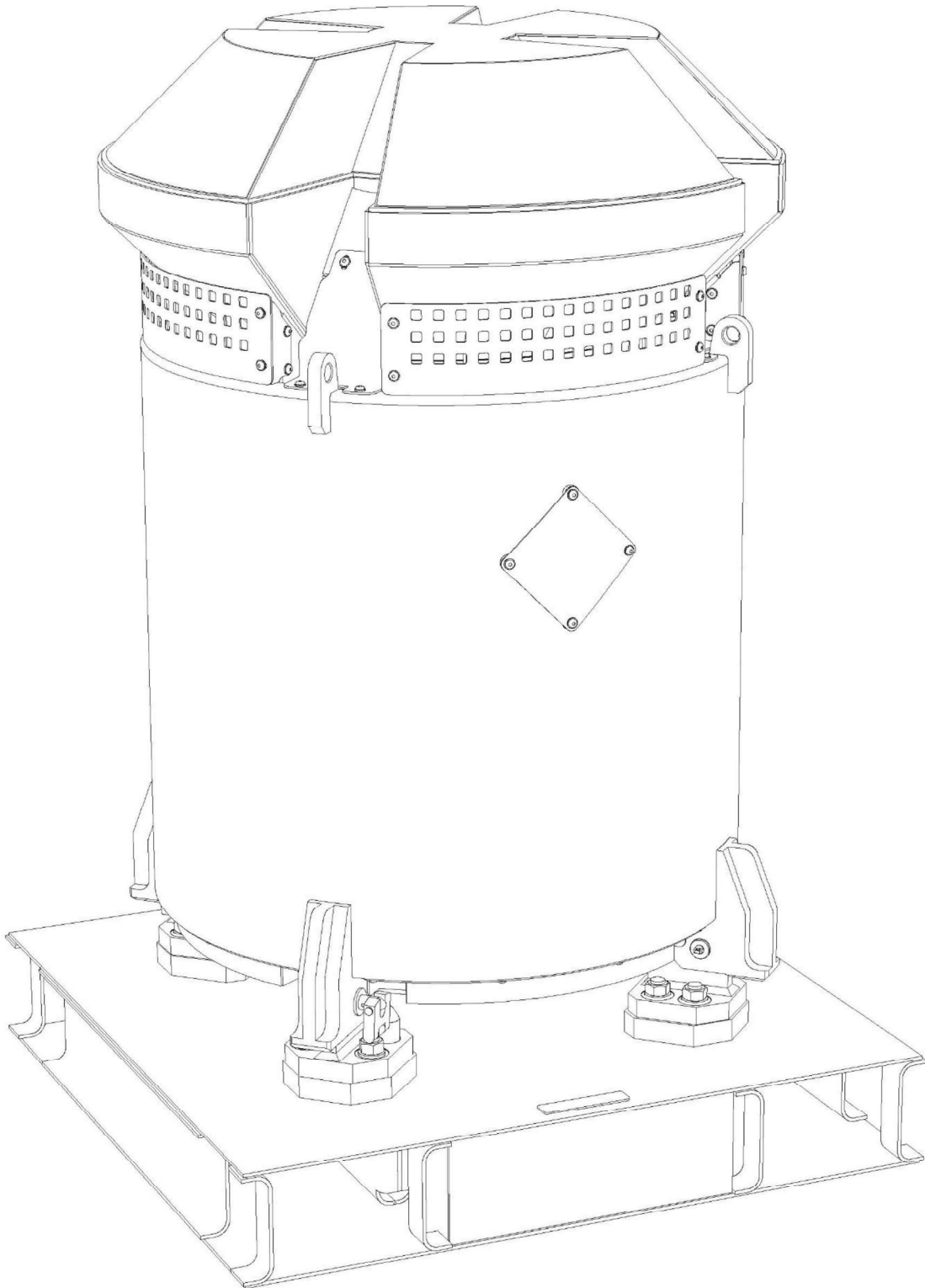
5. CERTIFICATE STATUS

Design approval issued to:

Synergy Health Sterilisation UK Ltd.
2200 Renaissance
Basing View
Basingstoke
RG21 4EQ
UK

Revision Number	Date of Issue	Date of Expiry	Reason for Revision
0	01 April 2022	31 March 2027	First Issue

APPENDIX 1 – PACKAGE ILLUSTRATION





U.S. Department of
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East Building, PHH-23
1200 New Jersey Ave, SE
Washington, D.C. 20590

CERTIFICATE NUMBER: USA/0844/B(U) -96

ORIGINAL REGISTRANT(S) :

STERIS Applied Sterilization Technologies
3951 Dayton Road
Madison, OH, 44057
USA