

# EC DECLARATION OF CONFORMITY

Legal Manufacturer	Siemens Medical Solutions USA, Inc. 2501 N. Barrington Road, Hoffman Estates, Illinois 60192 USA	
Developer/Manufacturing Facility	Siemens Medical Solutions USA, Inc. Molecular Imaging 2501 N. Barrington Road, Hoffman Estates, Illinois 60192 USA	
Authorized EU Representative	Siemens Healthcare GmbH Henkestraße 127 91052 Erlangen Germany	
Type of device	Single Photon Emission Computer Tomography System	
Medical device	Symbia Evo, Symbia Evo Excel Symbia S – software only update to installed base	
Product identification	see next page	
GMDN Code and Term	GMDN code 40640, Nuclear medicine system, gamma camera, stationary	
Classification	Class IIa (according to Annex IX to Council Directive 93/42/EEC)	

We declare that the above medical device is in conformity with the following Directive(s):

Council Directive 93/42/EEC.

The conformity of the full quality assurance system according to Annex II without Chapter II.4 is certified by:

BSI Group The Netherlands B.V.  
Say Building  
John M. Keynesplein 9  
1066 EP Amsterdam  
The Netherlands

The identification number of the notified body for implementation of the procedure set out in Annex II to the above Directive is 2797.

Directive 2011/65/EU of the European Parliament and of the Council

Relevant Harmonized Standard: EN 50581:2012

The declaration of conformity is issued under the sole responsibility of Siemens Medical Solutions USA, Inc.

This declaration supersedes any declaration issued previously for the same product.

Place and date	Hoffman Estates, IL	December 16, 2021
Name	Dr. James Williams (Head of Business Unit)	Steve Quam (Head of Quality Management)

Signature \_\_\_\_\_

For conditions of guarantee and liability please refer to our General Conditions of Sale.

DECLARATION OF CONFORMITY

**Product identification**

Product 1	Symbia Evo	Part No. 10910500 11006983
Product 2	Symbia Evo Excel	Part No. 10910501
Product 3: Software- only update to installed base	Symbia S	Part No. 08717741