

SAMSUNG BIOEPIS

Italian Patent and Trademark Office
Via Molise 19
00187 Rome
Italy

By certified email (only) to: dglcuibm.div07@pec.mise.gov.it

12 April 2024

Dear Italian Patent and Trademark Office

Update to notification pursuant to point (b) of Article 5(2) of Regulation (EC) No 469/2009 (as amended)

Please see below a further update to the notification originally made on 24 October 2023 pursuant to point (b) of Article 5(2) of Regulation (EC) No 469/2009 (as amended by Regulation (EU) 2019/933) and updated on 30 October 2023. A copy of this updated notification is also being sent by way of information to the certificate holder, Janssen Biotech, Inc.

ANNEX -Ia

Standard form for notification pursuant to points (b) and (c) of Article 5(2)

Tick the appropriate box	<input type="checkbox"/> New notification <input checked="" type="checkbox"/> Update of an existing notification	
(a) Name and address of the maker	Samsung Bioepis NL B.V. Olof Palmestraat 10, 2616 LR Delft, Nederland	
(b) Purpose of making	<input type="checkbox"/> Export <input type="checkbox"/> Storing <input checked="" type="checkbox"/> Export and storing	
(c) Member State in which making is to take place and Member State in which first related act (if any) prior to making is to take place	Member State of making	ITALY
	(Member State of first related act (if any))	ITALY
(d) Number of certificate granted in the Member State of making and number of certificate granted in Member State of first related act (if any) prior to making	Certificate of Member State of making	No. 132009901735337
	(Certificate of Member State of first related act (if any))	No. 132009901735337
(e) For medicinal products to be exported to third countries, reference number of marketing authorisation, or the equivalent of such authorisation, in each third country of export	CA, KR , UK. Reference numbers to be provided as soon as publicly available, in accordance with Article 5(5) (e) of Regulation (EC) No 469/2009 (as amended).	
	<u>KR: approval number: 14; approval code: 202400826</u>	
	<u>KR: approval number: 15; approval code: 202400827</u>	
	...?	

For and on behalf of Samsung Bioepis NL B.V.

Copy to: Janssen Biotech, Inc., 800 Ridgeview Drive, Horsham, PA 19044, USA (by post and email)
Copy to: Janssen Biotech, Inc. c/o Dr Modiano & Associates SpA, modianopartners@legalmail.it (by certified email).