LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Authorization

Date: 2023-06-21 Dnr: 5.9.1-2023-040789

Authorization to manufacture investigational medicinal products for humans

This permit is designed according to the principles in the Community Basic Format for Manufacturers Authorisation.

Permit number	5.9.1-2023-040789. Replaces 5.9.1-2022-074434.
Name of permit holder	**Cellcolabs AB**
Legal registration number	559312–6955
Manufacturing site address	Retzius väg 8 171 65 Solna
Permit holder's postal address	Retzius väg 8 171 65 Solna
Scope of the permit	Manufacture of ATMP from mesenchymal stem cells, cell suspension for injection/infusion for clinical trials.
Legal basis	Article 61 Regulation of the European Parliament and of the Council (EU) 536/2014 The Swedish Medical Products Agency's regulations (HSLF-FS 2021:102) on permits for the manufacture and import of medicines
Qualified person, name and title	**Gudmund Hedenskog, PhD** **Linda Ranehamn, Civ. Eng.**
Permit validity period	**2023-06-21 – 2027-12-08**

On behalf of the Swedish
Medical products Agency

Jonas Berggren
Unit Manager

John Boutelje
Pharmaceutical Inspector

This decision has been processed digitally and is therefore not signed. The authenticity of this permit can be verified by contacting the issuing authority.

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