

DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer.

We, Repolar Pharmaceuticals Oy, Nihtisillantie 3, 02630 Espoo, Finland hereby declare that our products

Abilar 10% Pihkasalva

Class IIb

to which this declaration relates, are in conformity with the essential requirements of the Medical Device Directive and the following Standards and Normative Documents:

Directive 93/42/EEC

Amendment 2007/47/EC

EN ISO 13485:2016

Laki terveydenhuollon laitteista 2010/629

Valviran määräykset terveydenhuollon laitteista ja tarvikkeista

MEDDEV 2.7.1 rev. 4.

EN ISO 10993-1:2009

GHTF/SG1/N70:2011

EN 1041:2008

EN ISO 15223-1:2016

EN ISO 14971:2012

The conformity of the product is assessed and the compliance with the standards is confirmed by Notified Body Eurofins Expert Services (0537).

Espoo 08.3.2023



Paavo Heikkinen
CEO, Repolar Pharmaceuticals Oy