Fisher Clinical Services GmbH
Im Wörth 3
79576 Weil am Rhein
Germany

QUALIFIED PERSON´S DECLARATION EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN THIRD COUNTRIES[1] (ARTICLE 13(3)(b) OF DIRECTIVE 2001/20/EC)

EudraCT number(s)	Name of the IMP(s)
2015-002340-14	• DMX-200 CAPSULES 120 MG Protocol: **REMAP CAP**

Manufacturing and/or Importation Authorisation (MIA) number[2] under which this declaration is made:

DE_BW_01_MIA_2021_0022/DE_BW_01_Fisher

Part A

Name of the IMP(s)	Manufacturing site(s) (Name and address where the activity is performed)	Activity performed at this site (including packaging, labeling and testing)
• DMX-200 CAPSULES 120 MG	Patheon Pharmaceuticals Inc By Thermo Fisher Scientific 2110 East Galbraith Road Cincinnati Ohio 45237, USA	• Manufacture and primary packaging
	Chemika Pty Ltd 119 Magowar Road Girraween NSW 2145, Australia	• Release and Stability testing (except for Germanium Dioxide Content)
	Analytical Resource Labs 520 S 850 E, Lehi, Utah 84043, USA	• Testing for Germanium Dioxide Content
	Fisher Clinical Services Inc. 7554 Schantz Road Allentown, Pennsylvania 18106-9052, USA	• Secondary packaging and labelling

[1] Countries other than EU Member States or contracting states of the European Economic Area (EEA)
[2] If no number is issued please state the name of the authorisation holder.

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Part B

I confirm that I am a QP and am authorised to make this declaration.
I declare that compliance with GMP at least equivalent to EU GMP has been verified on the basis of:

(i) Audit

Manufacturing site(s) (Name and address where the activity is performed)	**Auditing party**	**Date of last audit (completion)**
Patheon Pharmaceuticals Inc By Thermo Fisher Scientific 2110 East Galbraith Road Cincinnati Ohio 45237, USA	Patheon corporate audit	09 November 2018
Chemika Pty Ltd 119 Magowar Road Girraween NSW 2145, Australia	SeerPharma, consultant for Dimerix	06 May 2021
Analytical Resource Labs 520 S 850 E, Lehi, Utah 84043, USA	Fisher Clinical Services QP	20 May 2021
Fisher Clinical Services Inc. 7554 Schantz Road Allentown, Pennsylvania 18106-9052, USA	Patheon corporate audit	26 April 2019

(ii) If an audit of the site has not been performed, please provide a brief justification and explanation on how the QP knows that standards at least equivalent to EU GMP are being followed at the site[3].

Manufacturing site(s) (Name and address where the activity is performed)	**Justification**

This declaration is submitted by:

Signatory: _____ Date: 27 May 2021

Print Name: Claudia Kühn

Qualified Person

[3] E.g. assessment of documentation provided by the manufacturer, valid GMP certificate (EudraGMP), etc.