

DECLARATION OF CONFORMITY

Product: HYDRIM Accessory Products

Models:		Basic UDI-DI:
01-113625	Hydrim C61 Handpiece System, LCS	7540196C61LCSTGL
01-114405S	Hydrim M2 Handpiece System, LCS	7540196M2LCSUT
CS-HIPC	Cleaning Solution – HIP C51W 4x1.9L	7540196HIPFJ
CS-HIPC-U	HIP Ultra Solution – 8 x 750ml	7540196HIPFJ
CS-HIPL	Cleaning Sol. – HIP L110W 2x3.8	7540196HIPFJ

Classification: Class I (MDR Annex VIII, Rule 1)

Manufacturer: SciCan Ltd.
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 M3B 3P9 Canada

European Representative: SciCan GmbH
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 88299 Leutkirch Germany

We herewith declare that the above-mentioned products meet the provisions of the following EC legislation(s), and that SciCan Ltd. has exclusive responsibility for the content of this Declaration of Conformity. All supporting documentation is retained at the manufacturer’s premises.

General Applicable Legislation:

Medical Device Regulations: Regulation (EU) 2017/745 of 5 April 2017 on Medical Devices (MDR 2017/745, Annex IX, Chapters I and III)

Standards and Common Specifications:

EN ISO 13485:2016, EN ISO 14971:2019, EN 15223-1:2021, ISO 15883-1:2006 (Section 6.10)

This product also complies with: **IEC 60417:2002 DB, ISO 7000:2019**

Date CE Mark was affixed: May 26, 2021

Date of Effectiveness of Product Under this Declaration: August 16, 2023

Place: Toronto, Canada

Signature: _____

Date: August 16, 2023

Name & Title: Miguel Lopez, General Manager &VP of Operations, SciCan Ltd.