Part B
Document 3: Declaration of Conformity

DECLARATION OF CONFORMITY

Issuer's name: Xenopus Inc.
Issuer's address: 2 Prospect Road, Morrisburg ON, Canada K0C 1X0

Authorized European representative: **Tri Hawk S.A.**
Authorized European representative Address: Tri Hawk S.A., 6 rue Beck, 2ieme étage, Luxembourg, L-1222, Luxembourg

Object of the declaration: **Tri Hawk Carbide Bur,** a single use dental rotary instrument, a class IIA medical device following Annex V of the Directive 93/42/EEC

Applicable standards and normative documents: Xenopus Inc. declares that the object of the declaration above, Tri Hawk burs, are in conformity with the requirements of the following standards including all shape variants included in ISO 6360 table 1 and remain valid until May 26, 2024

Document number	Document Title	Edition/Date of issue
93/42/EEC	Medical Device Directive	1993.06.14
SOR/98-282	Medical Device Regulation	2020.06.23
13485:2016 (MDSAP Audit model Edition 2)	Medical Device Single Audit Program	
ISO 6360-2:2004	Dental Rotary Instruments Number Coding System	2004

Notified Body:
DQS Medizinprodukte GmbH, August- Schanz- Strasse 21, 60433 Frankfurt am Main.
EC Certificate Number: 170707412

CE **0297**

Signed for and on behalf of:
Xenopus Inc. Morrisburg, Ontario, Canada;

(Place and date of issue)
Joanne Kydd, COO

(Name, Function) (Signature or equivalent authorized by the issue

Part A
Document 2: Declaration of Conformity

DECLARATION OF CONFORMITY

Issuer's name: Xenopus Inc.
Issuer's address: 2 Prospect Road, Morrisburg ON, Canada K0C 1X0
Xenopus Inc. declares that the object of the declaration above, Tri Hawk burs, are in conformity with the requirements of the standards listed below and that our quality system follows Annex V-7 of the Directive 93/42/EEC

Document number	Document Title
93/42/EEC	Medical Device Directive

Authorized European representative: Tri Hawk S.A.
Authorized European representative Address: Tri Hawk S.A., 6 rue Beck, 2ieme étage, Luxembourg, L-1222, Luxembourg
Object of the declaration: **Tri Hawk Diamond,** a single use dental rotary instrument, a class IIA medical device under Annex IX rules 5 and 6.

Applicable standards and normative documents that were followed to confirm products' conformity with the essential requirements of the mentioned directive Annex I are detailed the technical file. and remain valid until May 26, 2024

Notified Body: DQS Medizinprodukte GmbH, August- Schanz- Strasse 21, 60433 Frankfurt am Main.
EC Certificate Number: 170707412

CE **0297**
Signed for and on behalf of: Xenopus Inc.

(Place and date of issue) Morrisburg Ontario, Canada

(Name, Function) Joanne Kydd (Signature or equivalent authorized by the issuer