DECLARATION OF CONFORMITY

1) Manufacturer:

Tobrix B.V.

Van Dijklaan 27
5581 WG Waalre
The Netherlands

2) Products

Surgical Laser Fibers for use in laser surgery applications *see appendix*

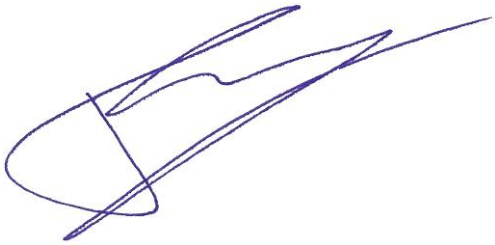
3) The products described above are in conformity with:

Title	Document No.
Medical Device Directive	93/42/EEC

4) Additional information

Conformity assessment procedure, Medical Device Directive Annex II (excluding section 4) for TXMFxxxxx and Medical Device Directive Annex V for TXAFxxxxx
Notified Body and NB-no: SGS UK number 0120
CE-certificate nr. BE13/223575198

Waalre 7/1/2015



AJC Stokbroekx, Managing Director

Appendix

Date: 2016/01/07

List of devices.

Device name	Type/ model/ref number	Risk class / rule[1]	First date of CE-marking
Radial fiber 400, Slim	TXMF400R	IIb/ rule 9	19-04-2015
Radial fiber 600, Regular	TXMF600R	IIb/ rule 9	19-04-2015
200mu surgical fiber glide round tip, dark hole, Single use	TXMFU200	IIb/ rule 9	09-01-2015
Bare Fiber 600 mu	TXAF600BFS TXAF600BFSPC	IIa/ rule 9	2013/07/09
Tulip-Tip Fiber 600mu	TXAF600BTS TXAF600BTSPC	IIa/ rule 9	2013/07/09

[1] See risk classification in Medical Device Directive, annex IX