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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

BIOTRONIK AG
Ackerstrasse 6
Bülach
8180
Switzerland

Facility ID Number: F000099

Holds Certificate No: **MDSAP 688646**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-10-11 Effective Date: 2024-10-11 Expiry Date: 2027-10-10

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 688646**

Registered Scope:

Design, development, manufacture, and distribution of the following sterile devices: PTCA balloon catheters, PTA balloon catheters, drug releasing PTCA balloon catheters, drug releasing PTA balloon catheters, coronary stents and stent systems, peripheral stents and stent systems, drug eluting coronary stents and stent systems, coronary guidewires, peripheral guidewires, drug-eluting resorbable coronary scaffolds and scaffold systems.

Original Registration Date: 2018-10-11 Effective Date: 2024-10-11 Expiry Date: 2027-10-10

Certificate No: **MDSAP 688646**

Location	Registered Activities
BIOTRONIK AG Ackerstrasse 6 Bülach 8180 Switzerland Facility ID Number: F000099	Design, development, manufacture, and distribution of following sterile devices; PTCA balloon catheters, PTA balloon catheters, drug releasing PTCA balloon catheters, drug releasing PTA balloon catheters, coronary stents and stent systems, peripheral stents and stents systems, drug eluting coronary stents and stents systems, coronary guidewires, peripheral guidewires, drug-eluting resorbable coronary scaffolds and scaffold systems.
Biotronik AG Ackerstrasse 2 Bülach 8180 Switzerland Facility ID Number: F000099	Design and development of the following sterile devices: PTCA balloon catheters, PTA balloon catheters, drug releasing PTCA balloon catheters, drug releasing PTA balloon catheters, coronary stents and stent systems, peripheral stents and stent systems, drug eluting coronary stents and stent systems, coronary guidewires, peripheral guidewires, drug-eluting resorbable coronary scaffolds and scaffold systems.

Original Registration Date: 2018-10-11 Effective Date: 2024-10-11 Expiry Date: 2027-10-10

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 760570 R000

Manufacturer: Biotronik AG

Address:
Ackerstrasse 6
Bülach
8180
Switzerland

Single Registration Number: CH-MF-000010176

EU Authorised Representative: BIOTRONIK SE & Co. KG

Address:
Woermannkehre 1
12359 Berlin
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-12-18**

Current Issue Date: **2025-04-30**

Starting Validity Date: **2025-04-30**

Expiry Date: **2028-12-17**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 760570 R000

Device Schedule:

Device Name: Synsiro Pro Sirolimus Eluting Coronary Stent System

Intended Purpose as per the Instructions for Use:
Synsiro Pro is intended to improve coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions.

Risk Classification: Class III Implantable

Type (Codes as per (EU) 2017/2185): MDN 1101

Basic UDI-DI: 76401304BUDI00020G9

Model	Catalogue Number	Stent Ø [mm]	Stent length [mm]	Nominal total drug load [ug]
Synsiro Pro 2.25/9	419155	2.25	9	55
Synsiro Pro 2.5/9	419156	2.5	9	55
Synsiro Pro 2.75/9	419157	2.75	9	55
Synsiro Pro 3.0/9	419158	3.0	9	55
Synsiro Pro 3.5/9	419159	3.5	9	70
Synsiro Pro 4.0/9	419160	4.0	9	70
Synsiro Pro 2.25/13	419161	2.25	13	80
Synsiro Pro 2.5/13	419162	2.5	13	80
Synsiro Pro 2.75/13	419163	2.75	13	80
Synsiro Pro 3.0/13	419164	3.0	13	80
Synsiro Pro 3.5/13	419165	3.5	13	95
Synsiro Pro 4.0/13	419166	4.0	13	95
Synsiro Pro 2.25/15	419167	2.25	15	93
Synsiro Pro 2.5/15	419168	2.5	15	93
Synsiro Pro 2.75/15	419169	2.75	15	93

First Issue Date: **2023-12-18**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 760570 R000

Model	Catalogue Number	Stent Ø [mm]	Stent length [mm]	Nominal total drug load [ug]
Synsiro Pro 3.0/15	419170	3.0	15	93
Synsiro Pro 3.5/15	419171	3.5	15	113
Synsiro Pro 4.0/15	419172	4.0	15	113
Synsiro Pro 2.25/18	419173	2.25	18	109
Synsiro Pro 2.5/18	419174	2.5	18	109
Synsiro Pro 2.75/18	419175	2.75	18	109
Synsiro Pro 3.0/18	419176	3.0	18	109
Synsiro Pro 3.5/18	419177	3.5	18	131
Synsiro Pro 4.0/18	419178	4.0	18	131
Synsiro Pro 2.25/22	419179	2.25	22	134
Synsiro Pro 2.5/22	419180	2.5	22	134
Synsiro Pro 2.75/22	419181	2.75	22	134
Synsiro Pro 3.0/22	419182	3.0	22	134
Synsiro Pro 3.5/22	419183	3.5	22	162
Synsiro Pro 4.0/22	419184	4.0	22	162
Synsiro Pro 2.25/26	419185	2.25	26	159
Synsiro Pro 2.5/26	419186	2.5	26	159
Synsiro Pro 2.75/26	419187	2.75	26	159
Synsiro Pro 3.0/26	419188	3.0	26	159
Synsiro Pro 3.5/26	419189	3.5	26	193

First Issue Date: **2023-12-18**

Current Issue Date: **2025-04-30**

Starting Validity Date: **2025-04-30**

Expiry Date: **2028-12-17**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 760570 R000

Model	Catalogue Number	Stent Ø [mm]	Stent length [mm]	Nominal total drug load [ug]
Synsiro Pro 4.0/26	419190	4.0	26	193
Synsiro Pro 2.25/30	419191	2.25	30	184
Synsiro Pro 2.5/30	419192	2.5	30	184
Synsiro Pro 2.75/30	419193	2.75	30	184
Synsiro Pro 3.0/30	419194	3.0	30	184
Synsiro Pro 3.5/30	419195	3.5	30	224
Synsiro Pro 4.0/30	419196	4.0	30	224
Synsiro Pro 2.25/35	419197	2.25	35	213
Synsiro Pro 2.5/35	419198	2.5	35	213
Synsiro Pro 2.75/35	419199	2.75	35	213
Synsiro Pro 3.0/35	419200	3.0	35	213
Synsiro Pro 3.5/35	419201	3.5	35	261
Synsiro Pro 4.0/35	419202	4.0	35	261
Synsiro Pro 2.25/40	419203	2.25	40	247
Synsiro Pro 2.5/40	419204	2.5	40	247
Synsiro Pro 2.75/40	419205	2.75	40	247
Synsiro Pro 3.0/40	419206	3.0	40	247
Synsiro Pro 3.5/40	419207	3.5	40	298
Synsiro Pro 4.0/40	419208	4.0	40	298

First Issue Date: **2023-12-18**

Current Issue Date: **2025-04-30**

Starting Validity Date: **2025-04-30**

Expiry Date: **2028-12-17**

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EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 760570 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-12-18	3564562	Issued
2024-08-16	30192301	Amended – Shelf-life extension
2024-12-19	30107441	Amended – Change to include additional indications
Current	30264361	Amended – Update to document in-use shelf-life extension of Sirolimus after in-house repackaging. Updates to Drug Master File for Sirolimus ancillary substance.

First Issue Date: **2023-12-18**

Current Issue Date: **2025-04-30**

Starting Validity Date: **2025-04-30**

Expiry Date: **2028-12-17**

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EU-Declaration of Conformity

DOC No. 24-02-03 Issue: 5

Manufacturer:	Biotronik AG Ackerstrasse 6 8180 Bülach Switzerland	Authorised Representative:	BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin Germany

Single Registration Number:	CH-MF-000010176
Product Category:	Drug-eluting coronary stent system
Product Name:	Synsiro Pro
Intended Purpose:	Synsiro Pro is intended to improve coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions.
Basic UDI-DI:	76401304BUDI00020G9
Applicable common specification:	Not applicable
Class:	III, according to Medical Device Regulation 2017/745, Annex VIII, rule 8 and 14
Conformity Assessment Route:	Medical Device Regulation 2017/745, Annex IX
Scope:	54 different variants. See list on next pages.

We hereby declare that the above-mentioned products meet the provisions of Medical Device Regulation 2017/745 for medical devices. All supporting documentation is retained under the premises of the manufacturer.

For these products the following EU-Technical documentation assessment certificate has been issued:

Certificate Number:	MDR 760570
Notified Body:	BSI Group The Netherlands B.V.
EEC No:	2797
Expiry date:	17.DEC.2028

To these products our approved Quality Management System according to Annex IX of the Medical Device Regulation 2017/745 is applied. For this Quality Management System the following certificate has been issued:

Certificate Number:	MDR 722508
Notified Body:	BSI Group The Netherlands B.V.
EEC No:	2797
Expiry date:	20.JUN.2026

Date of first CE-marking under council directive 93/42/EEC: 30.OCT.2019

EC Design Examination Certificate No. CE 708283

Place, Date of issue: Bülach, 08.MAY.2025

This declaration of conformity is issued under the sole responsibility of Biotronik AG.
Signature:

Marcel Schäfer, Ph.D.
Senior Director Regulatory Affairs and
Post Market Surveillance

Holger Ritzmann
Person Responsible for Regulatory Compliance

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Scope of DoC No. 24-02-03

Pos.	Designation	Unique Device Identifier (UDI-DI)	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Nominal total drug load [µg]
1	Synsiro Pro 2.25/9	07640130442153	419155	2.25	9	55
2	Synsiro Pro 2.5/9	07640130442160	419156	2.5	9	55
3	Synsiro Pro 2.75/9	07640130442177	419157	2.75	9	55
4	Synsiro Pro 3.0/9	07640130442184	419158	3.0	9	55
5	Synsiro Pro 3.5/9	07640130442191	419159	3.5	9	70
6	Synsiro Pro 4.0/9	07640130442207	419160	4.0	9	70
7	Synsiro Pro 2.25/13	07640130442214	419161	2.25	13	80
8	Synsiro Pro 2.5/13	07640130442221	419162	2.5	13	80
9	Synsiro Pro 2.75/13	07640130442238	419163	2.75	13	80
10	Synsiro Pro 3.0/13	07640130442245	419164	3.0	13	80
11	Synsiro Pro 3.5/13	07640130442252	419165	3.5	13	95
12	Synsiro Pro 4.0/13	07640130442269	419166	4.0	13	95
13	Synsiro Pro 2.25/15	07640130442276	419167	2.25	15	93
14	Synsiro Pro 2.5/15	07640130442283	419168	2.5	15	93
15	Synsiro Pro 2.75/15	07640130442290	419169	2.75	15	93
16	Synsiro Pro 3.0/15	07640130442306	419170	3.0	15	93
17	Synsiro Pro 3.5/15	07640130442313	419171	3.5	15	113
18	Synsiro Pro 4.0/15	07640130442320	419172	4.0	15	113
19	Synsiro Pro 2.25/18	07640130442337	419173	2.25	18	109
20	Synsiro Pro 2.5/18	07640130442344	419174	2.5	18	109
21	Synsiro Pro 2.75/18	07640130442351	419175	2.75	18	109
22	Synsiro Pro 3.0/18	07640130442368	419176	3.0	18	109
23	Synsiro Pro 3.5/18	07640130442375	419177	3.5	18	131
24	Synsiro Pro 4.0/18	07640130442382	419178	4.0	18	131
25	Synsiro Pro 2.25/22	07640130442399	419179	2.25	22	134
26	Synsiro Pro 2.5/22	07640130442405	419180	2.5	22	134
27	Synsiro Pro 2.75/22	07640130442412	419181	2.75	22	134

Pos.	Designation	Unique Device Identifier (UDI-DI)	Catalogue number (REF)	Stent diameter [mm]	Stent length [mm]	Nominal total drug load [µg]
28	Synsiro Pro 3.0/22	07640130442429	419182	3.0	22	134
29	Synsiro Pro 3.5/22	07640130442436	419183	3.5	22	162
30	Synsiro Pro 4.0/22	07640130442443	419184	4.0	22	162
31	Synsiro Pro 2.25/26	07640130442450	419185	2.25	26	159
32	Synsiro Pro 2.5/26	07640130442467	419186	2.5	26	159
33	Synsiro Pro 2.75/26	07640130442474	419187	2.75	26	159
34	Synsiro Pro 3.0/26	07640130442481	419188	3.0	26	159
35	Synsiro Pro 3.5/26	07640130442498	419189	3.5	26	193
36	Synsiro Pro 4.0/26	07640130442504	419190	4.0	26	193
37	Synsiro Pro 2.25/30	07640130442511	419191	2.25	30	184
38	Synsiro Pro 2.5/30	07640130442528	419192	2.5	30	184
39	Synsiro Pro 2.75/30	07640130442535	419193	2.75	30	184
40	Synsiro Pro 3.0/30	07640130442542	419194	3.0	30	184
41	Synsiro Pro 3.5/30	07640130442559	419195	3.5	30	224
42	Synsiro Pro 4.0/30	07640130442566	419196	4.0	30	224
43	Synsiro Pro 2.25/35	07640130442573	419197	2.25	35	213
44	Synsiro Pro 2.5/35	07640130442580	419198	2.5	35	213
45	Synsiro Pro 2.75/35	07640130442597	419199	2.75	35	213
46	Synsiro Pro 3.0/35	07640130442603	419200	3.0	35	213
47	Synsiro Pro 3.5/35	07640130442610	419201	3.5	35	261
48	Synsiro Pro 4.0/35	07640130442627	419202	4.0	35	261
49	Synsiro Pro 2.25/40	07640130442634	419203	2.25	40	247
50	Synsiro Pro 2.5/40	07640130442641	419204	2.5	40	247
51	Synsiro Pro 2.75/40	07640130442658	419205	2.75	40	247
52	Synsiro Pro 3.0/40	07640130442665	419206	3.0	40	247
53	Synsiro Pro 3.5/40	07640130442672	419207	3.5	40	298
54	Synsiro Pro 4.0/40	07640130442689	419208	4.0	40	298

Change History

Revision	Main changes from previous release to current release
A	New Document
B	Scope of DoC: UDI-DIs rectified to corresponding Synsiro Pro catalogue number
C	Shelf-life extension from two to three years according to amended EU Technical Documentation Assessment Certificate MDR 760570
D	Additional indications according to amended EU Technical Documentation Assessment Certificate MDR 760570
E	Updates to document in-use shelf-life extension of Sirolimus after in-house repackaging Updates to Drug Master File for Sirolimus ancillary substance