DECLARATION OF CONFORMITY

Manufacturer	Hemoteq AG Adenauerstrasse 15 52146 Würselen, Germany
Classification	Class III Product according to Annex IX of the MDD, rule 6, 13
Conformity Assessment Route	Annexes II.3 and II.4, per Article 11 of the MDD
Product	Agent™ MONORAIL™ Paclitaxel-Coated PTCA Balloon Catheter

Agent Catalog (UPN) Number*					
	Balloon length				
Balloon diameter	**8 mm**	**12 mm**	**15 mm**	**20 mm**	**30 mm**
2.00 mm	H74939222200810	H74939222201210	H74939222201510	H74939222202010	H74939222203010
2.25 mm	H74939222220810	H74939222221210	H74939222221510	H74939222222010	H74939222223010
2.50 mm	H74939222250810	H74939222251210	H74939222251510	H74939222252010	H74939222253010
2.75 mm	H74939222270810	H74939222271210	H74939222271510	H74939222272010	H74939222273010
3.00 mm	H74939222300810	H74939222301210	H74939222301510	H74939222302010	H74939222303010
3.25 mm	H74939222320810	H74939222321210	H74939222321510	H74939222322010	H74939222323010
3.50 mm	H74939222350810	H74939222351210	H74939222351510	H74939222352010	H74939222353010
3.75 mm	H74939222370810	H74939222371210	H74939222371510	H74939222372010	H74939222373010
4.00 mm	H74939222400810	H74939222401210	H74939222401510	H74939222402010	H74939222403010

Agent GTIN Number*					
	Balloon length				
Balloon diameter	**8 mm**	**12 mm**	**15 mm**	**20 mm**	**30 mm**
2.00 mm	08714729831396	08714729831402	08714729831419	08714729831426	08714729831433
2.25 mm	08714729831440	08714729831457	08714729831464	08714729831471	08714729831488
2.50 mm	08714729831495	08714729831501	08714729831518	08714729831525	08714729831532
2.75 mm	08714729831549	08714729831556	08714729831563	08714729831570	08714729831587
3.00 mm	08714729831594	08714729831600	08714729831617	08714729831624	08714729831631
3.25 mm	08714729831648	08714729831655	08714729831662	08714729831679	08714729831686
3.50 mm	08714729831693	08714729831709	08714729831716	08714729831723	08714729831730
3.75 mm	08714729831747	08714729831754	08714729831761	08714729831778	08714729831785
4.00 mm	08714729831792	08714729831808	08714729831815	08714729831822	08714729831839

* UPN and GTIN are different article number codes representing the same product model

Hemoteq AG
Adenauerstrasse 15
52146 Würselen
Germany

Contact
Phone
+49 (0)2405-45 50 00
Fax
+49 (0)2405-45 50 12

Banking Account
Commerzbank Düsseldorf
BLZ: 300 400 00
Konto: 170 894 000
IBAN: DE62 3004 0000 0170 8940 00
BIC: COBADEFFXXX

District Court Aachen
HRB 13990
VAT ID No.
DE 205600891
Taxnumber
202/5825/0485

Chief Executive Officer
Dr. Michael Hoffmann
Chief Finance Officer
Dr. Peter Sieb
Chairman of the Supervisory Board
Dr. Max Gisbert Kley

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

Standards Applied

List of (harmonized) Standards for which documented evidence of compliance can be provided according to LOS 111209 179 a

Notified Body

DEKRA Certification B.V.
Meander 1051,
6825 MJ Arnhem
P.O. Box 5185,
6802 ED Arnhem,
The Netherlands
Notified Body ID No. 0344

Certification Body (ISO 13485)

TÜV Süd Product Service GmbH
Zertifizierstelle
Ridlerstraße 65
80339 München
Germany

Certification Body (MDSAP)

TÜV Süd America Inc.
10 Centennial Drive Ste 207
Peabody, MA 01960
USA

(EC) Certificate(s)

Certificate Name	Certificate Number
Annex II.3	Registration No.: 3817434 CE 02
Annex II.4	Registration No.: 3817434 DE 03 Report No.: 3820034-TDR03-R4

ISO Certificate(s)

Certificate Name	Certificate Number
EN ISO 13485: 2016	Q5 046012 0013 Rev. 00

MDSAP Certificate(s)

Certificate Name	Certificate Number
ISO 13485: 2016	QS6 046012 0014 Rev. 00

Start of CE Marking (CE 0123) Lot number of the first CE-marking:
Lot 1948H14 (TÜV Süd NB ID No. 0123)

End of CE Marking (CE 0123) Date, Lot number or serial number of the last CE-marking:
Last manufacturing batch 18.1127 of June15th 2018, last lot 4838H18; (TÜV Süd NB ID No. 0123)

Start of CE Marking (CE 0344) First Manufacturing batch 18.1477 of August 7th 2018, first lot 6655H18 (DEKRA NB ID No. 0344)

Scope of application All devices covered by product certificates valid at the time of manufacture are subject to monitoring and surveillance by DEKRA certification B.V. (NB ID No. 0344) as of 5 February 2018. Ending with manufacturing date of June 15th , 2018 all products within the scope of this DoC bear the CE mark of TÜV Süd (CE 0123), based on the contractual regulations regarding the label transition phase between Hemoteq and the former (CE 0123) and current (CE 0344) Notified Body.
After manufacturing date of June 15th , 2018 all products within the scope of this DoC bear the CE mark of DEKRA (CE 0344), based on the contractual regulations regarding the label transition phase between Hemoteq and the former (CE 0123) and current (CE 0344) Notified Body.
Effective date of the labeling changeover was July 27th 2018.

Valid until: 26th of May, 2024

Place, Date of Issue Würselen, 12th of July, 2019

Name	Position	Date	Signature
Dr. Michael Hoffmann	CEO	15th of July 2019	

Hemoteq AG
Adenauerstrasse 15
52146 Würselen
Germany

Contact
Phone
+49 (0)2405-45 50 00
Fax
+49 (0)2405-45 50 12

Banking Account
Commerzbank Düsseldorf
BLZ: 300 400 00
Konto: 170 894 000
IBAN: DE62 3004 0000 0170 8940 00
BIC: COBADEFFXXX

District Court Aachen
HRB 13990
VAT ID No.
DE 205600891
Taxnumber
202/5825/0485

Chief Executive Officer
Dr. Michael Hoffmann
Chief Finance Officer
Dr. Peter Sieb
Chairman of the Supervisory Board
Dr. Max Gisbert Kley