Technical and other documentation regarding EC type examination certificate 13419PRS01rev1

The document list has been updated on 2019-04-04.

Product names: DOTpro 460+ A2B2E2,
DOTpro 460 K3,
DOTpro 460 A3AX,
DOTpro 460+ A2B2E2AX, and
DOTpro 460+ A2B2E2K2

Applicant: JSC Sorbent

Item of documentation	*Document identification*	*Assessment*
1. Application for the EC type examination	JSC Sorbent, Boris Dubovik, 2013-04-02 and 2016-10-12	Adequate
2. Product drawings, construction, and material lists	Product descriptions: Technical specifications TU 2568-567-05795731-2013, received 2019-03-04 Product flow scheme, received 2013-08-30 Assembly drawings: YaKPV 19103.00.00 + -01 + -02 + -03 + -04 + -05 YaKPV 19103.01.00 + -01 + -02 + -03 + -04 + -05 YaKPV 19103.01 including material lists List of materials for manufacturing gas filters DOTpro 460 A3AX	The products and materials are identified.
3. Compliance with Directive 89/686/EEC relevant basic requirements	The compliance assessment is based on reports mentioned below items 3.1-3.11	
3.1 FIOH assessment of relevant Directive basic requirements	2013-10-21 and 2016-12-02	The applied harmonised standard EN 14387:2004+A1:2008 supports the relevant requirements.
3.2 D. I. Mendeleev Institute for Metrology PPE testing laboratory, test report	No. 95/13, 2013-06-05 for DOTpro 460+ A2B2E2 and DOTpro 460 K3	Requirements of the standard EN 14387:2004+A1:2008 are fulfilled.
3.3 D. I. Mendeleev Institute for Metrology PPE testing laboratory, test report	No. 239/13, 2013-10-31 for DOTpro 460+ A2B2E2AX and DOTpro 460 A2B2E2K2	Requirements of the standard EN 14387:2004+A1:2008 are fulfilled.
3.4 JSC Sorbent, Quality Control Department	Test report 219 2013-04-24, DOTpro 460+ A2B2E2 2013-04-24 for hydrogen cyanide	Test was witnessed by Erja Mäkelä from the FIOH and fulfilled the requirements of the standard EN 14387:2004+A1:2008.
3.5 Monitoring LTD. PPE testing laboratory, test report	No. 0239/16, 17/11/2016	Requirements of the standard EN 14387:2004+A1:2008 are fulfilled.

Item of documentation	*Document identification*	*Assessment*
3.6 FIOH	Report of the witnessing testing at JSC Sorbent 2013-05-23	The report is adequate.
3.7 JSC Sorbent, Quality Control Department	Test report 440 2013-07-31 DOTpro 460+ A2B2E2K2 for hydrogen cyanide	Tatiana Kostikian from D. I. Mendeleev Institute for Metrology PPE testing laboratory witnessed the testing and signed the test report on request of the FIOH. The test report and witnessing meets the requirements.
3.8 JSC Sorbent, Quality Control Department	Test report 433 2013-07-31 DOTpro 460+ A2B2E2AX for hydrogen cyanide	Tatiana Kostikian from D. I. Mendeleev Institute for Metrology PPE testing laboratory witnessed the testing and signed the test report on request of the FIOH. The test report and witnessing meets the requirements.
3.9 Draft information sheet	RE 2568-584-05795731-2013, received 2019-03-04	The document fulfils the requirements of the Regulation EU 2016/425.
3.10 Product markings	Draft markings on product and on package, received 2013-08-05 and 2013-10-30. Picture of product marking A3AX received 2016-11-30	The markings fulfil the requirements of the Regulation EU 2016/425.
3.11	Risk Assessment for Gas Filter DOTpro 460	The document fulfils the requirements of the Regulation EU 2016/425.
4. Description of the production quality system and related product control and test facilities	Documents below: 4.1-4.2	Adequate for category III requirements.
4.1 Description of the production quality system and related product control and test facilities	Technical specifications TU 2568-567-05795731-2013, received 2019-03-04 Product flow scheme, received 2013-08-30	Description of the production procedure and checks and testing to be made for the product are documented.
4.2 Fulfilling the Directive 89/686/EEC article A		Article 11A compliance control yearly since 2014 by the FIOH for 4 filter types. DOTpro A3AX control started in 2017. Agreement on module C2 in accordance with the Regulation EU 2016/425 with the FIOH in 2019.

End of documentation list.

Finnish Institute of Occupational Health
Notified Body 0403

P. O. Box 40
(Topeliuksenkatu 41b, Helsinki)
FI-00032 TYÖTERVEYSLAITOS
Finland

Tel. +358 - 30 - 4741
Fax +358 - 30 - 474 2115
e-mail: firstname.lastname@ttl.fi
www.ttl.fi