

Mitsubishi Chemical Advanced Materials Compliance Department I.P. Noord – Galgenveldstraat 12 B-8700 Tielt T: +32 (0)51/ 42.35.45 Regulatorysupport.mcam@mcgc.com

ABSENCE DECLARATION (PFAS)

Date: 17 October 2023 (¹) Version 1.0 Products: the Mitsubishi Chemical Advanced Materials stock shapes mentioned below: Ketron[®] LSG PEEK natural and black Ketron[®] LSG PEEK Food Grade natural and black Ketron[®] LSG CA30 PEEK Sultron[®] LSG PPSU R5100 natural NT15 and black BK937 Sultron[®] LSG PPSU R5500 blue BU1027, green GN1007, grey GY1037, natural NT15, orange OR1145, red RD1018 and yellow YL1337 Duratron[®] LSG PEI natural, black and blue Sultron[®] LSG PSU natural Proteus[®] LSG H PP natural

To the best of our knowledge, we herewith confirm that **PFAS (Per- and polyfluoroalkyl substances) and related substances** are not intentionally introduced² during the production of the above mentioned **Mitsubishi Chemical Advanced Materials stock shapes**.

Since the presence of the above mentioned substances cannot reasonably be expected, Mitsubishi Chemical Advanced Materials does not systematically check their absence in its stock shapes by testing.

MCAM.COM

1/2

¹ This statement expires in case of regulatory or compositional changes. New statements are published on our website in case of alterations; previous statements then automatically become void. Please always consult our website for the latest version.

² "Intentionally introduced" means "deliberately utilised in the formulation of a material to facilitate manufacture or to provide a specific characteristic, appearance or quality".



Mitsubishi Chemical Advanced Materials Compliance Department I.P. Noord – Galgenveldstraat 12 B-8700 Tielt T: +32 (0)51/ 42.35.45 Regulatorysupport.mcam@mcgc.com



Duratron[®], Ketron[®], Proteus[®] and Sultron[®] are registered trademarks of the Mitsubishi Chemical Advanced Materials Group. PEEK-CLASSIX[™] is a trademark of Invibio Ltd.

All statements, technical information, recommendations, and advice are for informational purposes only and are not intended and should not be construed as a warranty of any type or term of sale. The reader, however, is cautioned that Mitsubishi Chemical Advanced Materials does not guarantee the accuracy or completeness of this information and it is the customer's responsibility to test and assess the suitability of the products of Mitsubishi Chemical Advanced Materials in any given application or for use in a finished device.

The products of Mitsubishi Chemical Advanced Materials should not be used for applications involving medical devices that are intended to remain implanted in the human body continuously for a period exceeding 24 hours (30 days*), or are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days*), or as critical components of medical devices that are essential to the continuation of human life.

*: "30 days" applies to Ketron[®] PEEK-CLASSIX[™] LSG white only.

Mitsubishi Chemical Advanced Materials is not a medical device manufacturer and the information herein does not constitute any express or implied warranties or representations whatsoever, including, but not limited to, all warranties provided for by any applicable law, any implied warranty of merchantability, of fitness for a particular purpose, any warranty against hidden defects or redhibitory defects or vices, or that the products of Mitsubishi Chemical Advanced Materials are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in implantable medical device applications and in applications that are essential to the restoration of or continuation of a bodily function important to the continuation of human life.

PEEK-CLASSIX[™] is a trademark of Invibio Ltd.

Mitsubishi Chemical Advanced Materials

MCAM.COM

2/2