

Zernikedreef 2
2333 CL Leiden
The Netherlands

Friday June 3, 2016,

From: / MENTOR

To: / ANSM

Purpose: Urgent – Breast Implants pre-filled with silicone gel. Sales and data ALCL. (20/05/2016)

Reference: MV-Demande aux fabricants

Dear Sir,

Following your urgent request regarding:

1. The number of units of breast implants pre-filled with silicone gel marketed under the names and brands of MENTOR MEDICAL SYSTEMS B.V, including the brands that may have been bought by this Company, for the last twelve years of marketing until the 31st December of 2015.
2. The total number of *Anaplastic Large Cells Lymphoma (ALCL)* cases reported to MENTOR MEDICAL SYSTEMS B.V, involving or likely to involve breast implants pre-filled with silicone gel marketed under the names and brands of this Company, including the brands that may have been bought by this Company, for the last twelve years of marketing until the 31st December of 2015.

Included are the following:

1. ANNEX I – Sales data (2011- 2015) and ALCL reported cases for Perouse Plastie (2004-2015). Due to the manual process for sales data from 2004-2010, we kindly request an extension to Friday June 10, 2016 to complete gathering the sales information.
2. ANNEX II – Sales data (2004- 2015) and ALCL reported cases (2004-2015) for Mentor Gel® Products manufactured in Leiden, Netherlands.
3. ANNEX III - Sales data (2004- 2015) and ALCL reported cases (2004-2015) for Mentor Products manufactured in Texas, USA
4. ANNEX IV - Sales data (2004- 2015) and ALCL reported cases (2004-2015) for Mentor Saline® Products manufactured in Texas, USA

Please consider that the information provided is Mentor confidential. Mentor needs to approve and be notified before any publication of the data outside your Agency. We thank you in advance for your cooperation on this request.

Please don't hesitate to contact _____ or _____ with any additional information.

Sincerely,

MENTOR Director, Quality and Compliance