Professor Vlastimil Válek
Deputy Prime Minister and Minister of Health
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Brussels, 26 October 2022

Re: Implementation of the EU Medical Device Regulation 745/2017 (MDR) – Urgent Need for Legislative Action

Dear Deputy Prime Minister Válek,

As industry leaders of the medical technology industry, we would like to reiterate our serious concerns regarding the current implementation status of the Medical Devices Regulation 2017/745 (MDR).

Unless immediate action is taken, Europe faces a scenario where a high number of existing medical devices, upon which patients, hospitals and other health institutions rely, will fail to be re-certified on time and therefore risk to permanently disappear from the market. At the same time, certification of new and improved products is also delayed, resulting in delayed patient access to the benefits of innovation.

We therefore call upon you to urgently support and introduce measures of *legislative nature* (i.e., via formal amendment of the MDR) to safeguard the continuity of patient care across Europe and the world.

After more than five years of implementation, the MDR regulatory system still lacks sufficient certification capacity needed to certify

1) Existing devices that have been on the market for years and that are required to undergo re-certification under the Regulation by no later than 26 May 2024 and
2) New or significantly changed devices.

There are around 25,000 certifications under the former Medical Devices Directives covering hundreds of thousands of existing devices. As of today, only a small fraction of these former certifications has been replaced with the needed MDR certifications. To make things worse, more and more of these former certifications are expiring, with two thousand expiring now in 2022, double that amount in 2023, and more than seventeen thousand expiring in the first four months of 2024.

The ongoing COVID-19 pandemic and the war in Ukraine have exacerbated this situation by creating supply chain disruptions, issues with conducting on-site audits and with clinical investigations.

Since the EU Employment, Social Policy, Health and Consumer Affairs Council meeting of June 2022, national regulatory authorities in the Medical Devices Coordination Group have proposed 19 (non-legislative) measures via the paper MDCG 2022-14, which are designed to free up some Notified Body capacity.

Although we welcome this rapid work, it is our unequivocal assessment that these 19 solutions are insufficient. They only partially address the structural issue of Notified Body capacity, and they fail to directly address the growing emergency of expiring certifications. They also fail to provide a workable regulatory pathway for new devices whose technological innovation can bring needed solutions to Europe's pressing healthcare challenges.

Legislative solutions are therefore needed as soon as possible*, in addition* to the non-legislative work conducted thus far. Specifically, we urge the EU institutions to take legislative action to:

(1) **Extend the validity of the Medical Devices Directive and Active Implantable Medical Devices Directive Certificates**: to maintain access to existing devices. These extensions should be given in a similar manner to the January 2022 amendment of the *in vitro* Diagnostic Medical Devices Regulation, i.e., with different deadlines for each device risk class.
(2) **Allow conditional/temporary MDR certification**: to maintain access to existing devices, substantially changed and new devices, for example by allowing time to finish compiling further data/evidence needed to meet MDR requirements
(3) **Abolish the MDR Article 120(4) 'warehousing' deadline:** to allow the continued sale of existing devices beyond the May 2025 end-date, provided that they are manufactured before the 26 May 2024. This will allow to avoid needless disposal of devices already placed on the market.

We strongly encourage you to swiftly embrace these measures, but also to continue working to strengthen the role of Europe as an attractive region of the world for investments in medical technology innovations. This could be achieved by setting as a priority timely patient access to best-in-class breakthrough technologies which address unmet medical needs through clear regulatory pathways.

Taking into account this situation, we, the signatories of this letter, call on you to work on concrete legal solutions that allow us to comply in time with the new MDR requirements. We stand ready to collaborate, to individually meet with you and discuss solutions that address the many complex challenges.

Best regards,

Cc:

- **MEP Peter Liese,** ENVI Coordinator for the EPP
- **MEP Tiemo Wölken,** ENVI Coordinator for S&D
- **MEP Nils Torvalds,** ENVI Coordinator for Renew
- **MEP Bas Eickhout,** ENVI Coordinator for Greens/EFA
- **MEP Alexandr Vondra,** ENVI Coordinator for ECR
- **Stella Kyriakides**, Commissioner for Health and Food Safety, European Commission
- **Thierry Breton**, Commissioner for Internal Market, Industry, Entrepreneurship and SMEs, European Commission
- **Mariya Gabriel,** Commissioner for Innovation, Research, Culture, Education and Youth, European Commission

Please note: we are sending this same letter to fellow Ministers across the European Union

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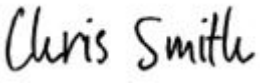

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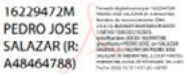

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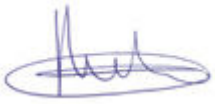

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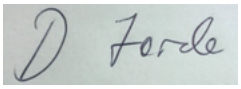

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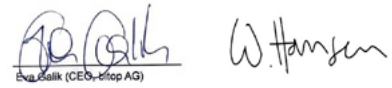

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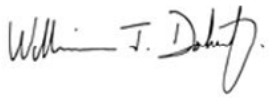

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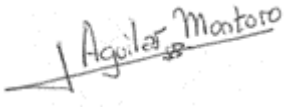

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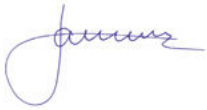

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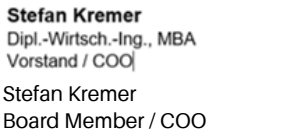

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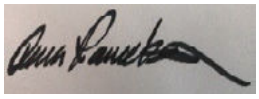

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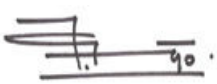

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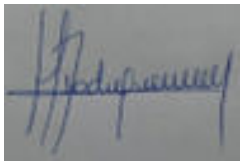

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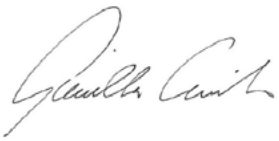

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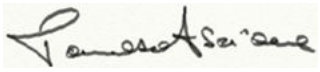

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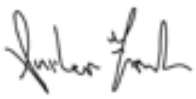

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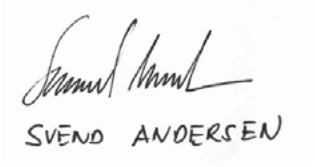

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Managing Director
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Wolfgang Steimel
Chief Executive Officer
Polytech Health & Aesthetics GmbH

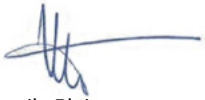
Bruno Privat
Président
Precilens

Manuel Alfonso Fernández
Chief Executive Officer
Proclinic Group

Benjamin Binot
President, Oral Care Europe
Procter & Gamble

Ralf Klein
Geschäftsführer/ Chief Executive Officer
Radimed GmbH

Mikael Sälg
Chief Executive Officer
Rekal Svenska AB



Lucile Blaise
President-Sleep & Respiratory Care
Resmed

Esperanza Nolasco Bethencourt
Sole Director
RGB Medical Devices

Jürgen Steinbeck
Geschäftsführer | Co-Chief Executive Officer
Richard Wolf GmbH

Dalimil Žurek
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Roche d.o.o.

Amanda LoGuidice
Vice President, QA/RA & Product Science
RTI Surgical

Ing. Aldo Angeletti
Presidente e Legale Rappresentante
S.A.L.F. S.p.A. Laboratorio Farmacologico

Paul Martingell
SVP Region Head Europe
Sanofi Consumer Healthcare

Paola Oddenino
President
Sapi Med SPA

Carlota Fernández Durán
Directora General
Sapio Life

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Scott Brown
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Torbjörn Kronander
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Torbjörn Kronander
President and Chief Executive Officer
Sectra AB

Pia Renaudin
Chief Executive Officer
Senzime AB

Stefan Pfeiffer
Managing Director/Chief Executive Officer and Partner
SERAG-WIESSNER GmbH & Co. KG

Dr. Daniel O'Mahony
Partner
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Dermot Scanlon
Chief Executive Officer
Serosep

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Ημερομηνία: 2022.10.10 13:34:26 EEST
Diana Mochintra
General Manager
SIDAPHARM P.C.
Ophthalmic & Medical Disposable Products
Diana Mochintra
General Manager
Sidaphram PC

Antoni Picó Genestar
General Manager
SIBEL

Fabrizio Chines
Chairman & Chief Executive Officer
SIFI S.p.A.

Susanne Siedler
Managing Director
Signus Medizintechnik

Miličević, Vladimir
Managing director
Simps´S d.o.o.
SIMPS'S
Vladimir Miličević
Managing Director
SIMPSS d.o.o.

Francis Jannot
Executive Vice President, International Sales
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General Manager
Waldemar Link Espana S.A.

André Schulte
Chief Executive Officer Group
WEINMANN Emergency Medical Technology GmbH + Co. KG

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Legale Rappresentante
Welcare Industries SpA

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Wise S.r.l.

Przemysław Wolicki
Prezes Zarzadu
WSR Comfort sp. z o.o.

Jasna Sturm
Digitalno podpisal Jasna Sturm
Datum: 2022.10.06 11:38:27 +02'00'
Jasna Šturm, CEO
Zaloker & Zaloker d.o.o.

Jasna Šturm
Chief Executive Officer
ZALOKER & ZALOKER d.o.o.

Mats Palerius
Chief Executive Officer
Zenicor Medical Systems AB

Alejandro del Valle
Chief Executive Officer
Ziacom

Wilfred van Zuilen
President EMEA
Zimmer GmbH